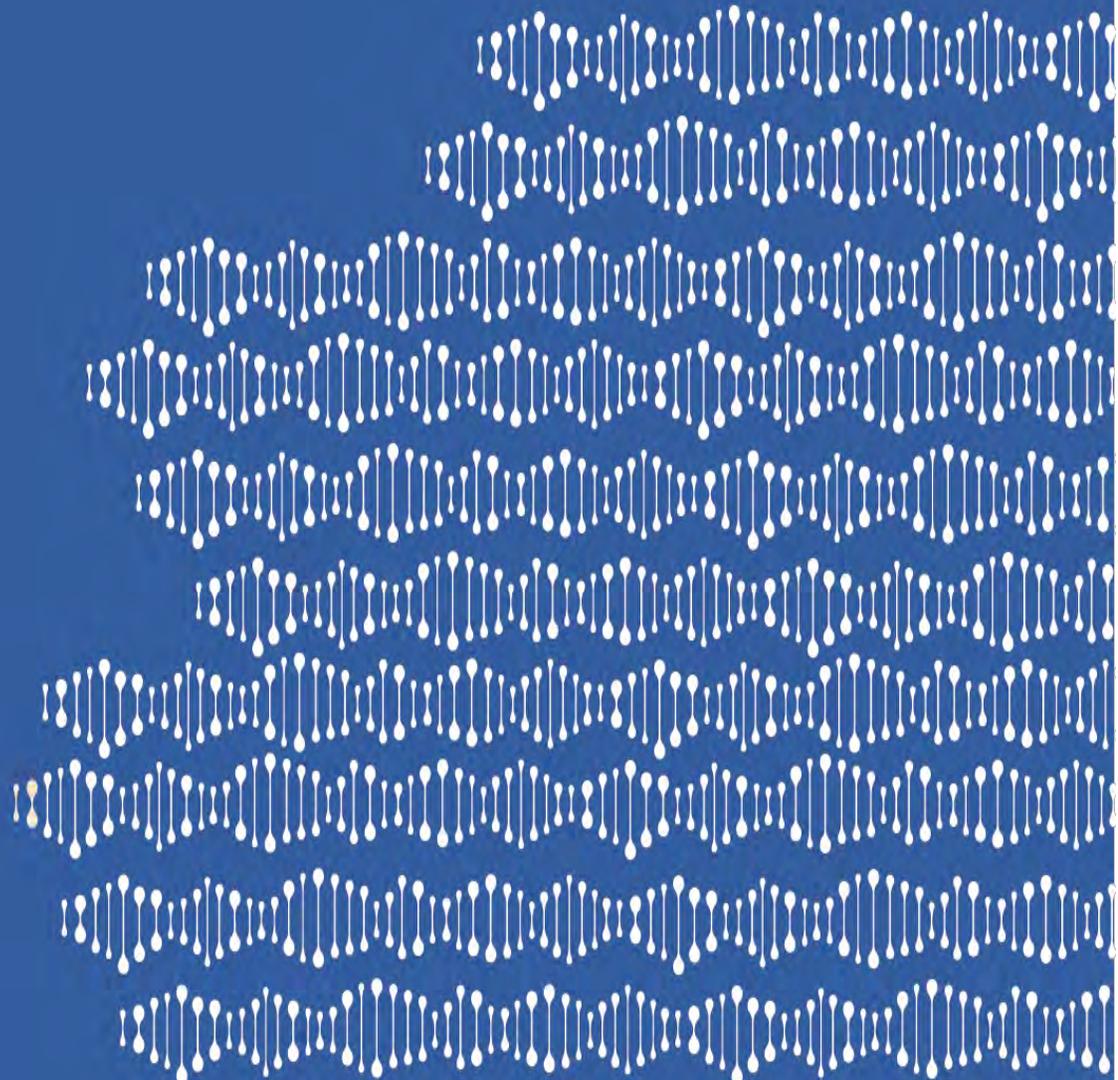




CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

February 17, 2021





Summary Overview of the February 17, 2021, Oversight Committee Meeting

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the February 17, 2021, Oversight Committee meeting.

Grantee Presentations

Two CPRIT grantees will present updates on their CPRIT-funded projects:

- Abbey B. Berenson, M.D., Ph.D., professor, Departments of Obstetrics & Gynecology and Pediatrics, Director, Center for Interdisciplinary Research in Women's Health, and The Ruth Hartgraves MD Chair in Obstetrics & Gynecology at The University of Texas Medical Branch at Galveston
- Michael Curran, Ph.D., associate professor, Department of Immunology, Division of Basic Science Research, The University of Texas MD Anderson Cancer Center, founder of CPRIT grantee ImmunoGenesis and James Barlow, ImmunoGenesis CEO

CEO Report

Wayne Roberts will present the CEO's report and address issues including COVID-19, personnel, FY 2021 grant funds available, the legislative session, the Chief Scientific Officer search process, CPRIT's 2020 Annual Report, and other topics. Mr. Roberts will also present his annual report required by Tex. Health & Safety Code § 102.260(c).

Chief Compliance Officer Report

Vince Burgess will report on the status of required grantee reports, financial status report reviews, desk reviews, site visits, annual compliance attestation, audit tracking, and training. He will also certify that the proposed academic research awards complied with statutory and administrative rule requirements.

Chief Scientific Officer Report and Grant Award Recommendations

Dr. Jim Willson will provide an update on the Academic Research Program and present the Program Integration Committee's (PIC) two Recruitment of Established Investigators award recommendations totaling \$12 million.

CPRIT does not publicly disclose information related to the Academic Research grant applications recommended for funding until the Oversight Committee meeting. The information is available to board members through a secure electronic portal.

Chief Prevention Officer Report

Ms. Ramona Magid will update the Oversight Committee on the on the agency's prevention program and present the FY 2022 prevention requests for applications for approval.

Chief Product Development Officer Report

Dr. Cindy WalkerPeach will provide an update on the product development program the FY 2022 product development requests for applications for approval.

Internal Auditor Report

Weaver and Tidwell, CPRIT's internal auditor, will provide an internal audit update.

Appointments - Scientific Research and Prevention Programs Committee

Mr. Roberts has provisionally appointed three new members to CPRIT's Scientific Research and Prevention Programs Committees. CPRIT's statute requires the Oversight Committee to approve the CEO's recommendation before the appointments are final. CPRIT has provided the appointees' biographical sketches for the Oversight Committee's consideration.

Proposed Amendments to 25 TAC Chapters 703

Cameron Eckel will present the final order for amendments to Chapter 703 that the Oversight Committee provisionally approved at its meeting in November. She will also present two proposed changes to Chapters 702 and 703 administrative rules for Oversight Committee consideration and approval to publish in the *Texas Register*.

Chief Operating Officer Report

Heidi McConnell will discuss the operating budget, performance measures, and debt issuance history for the first quarter of FY 2021.

Search Firm Contract Approval

Ms. McConnell will present CPRIT staff's recommendation regarding a proposed contract for executive search firm services.

Communications Update

Chris Cutrone will update the Oversight Committee on CPRIT's communication efforts, including coverage of the agency and grantees in earned media, digital media, and social media.



Oversight Committee Meeting Agenda

February 17, 2021
9:00 a.m.

This Meeting Will Be Conducted by Videoconference and Telephonically

In accordance with Texas Government Code Section 418.016, Governor Abbott has suspended various provisions that require government officials and members of the public to be physically present at a specified meeting location.

Members of the public may connect to the meeting by going to the URL: <https://www.zoomgov.com/j/1605279444?pwd=Tkp3Q1pKaWxhUEpiNm00aGd3YjIeZz09>

The public may also join via telephone audio only using the following:
US: +1 669 254 5252 or +1 646 828 7666 or +1 551 285 1373 and entering the **Webinar ID** of **160 527 9444** when prompted.

A recording of the meeting will be available after the meeting on CPRIT's public website. CPRIT will provide an electronic copy of the agenda packet at <https://cprit.texas.gov/oversight-committee/meetings/> by February 15.

A member of the public wishing to comment during the meeting must contact Melanie Cleveland (mcleveland@cprit.texas.gov) at least 30 minutes prior to the posted meeting start time. When the Oversight Committee reaches the "Public Comment" agenda item, the Chair will recognize each person requesting to provide public comment by name. The Chair may limit the amount of time a member of the public may speak. CPRIT cannot guarantee that an individual contacting Ms. Cleveland less than 30 minutes before the posted start time may provide public comment.

The Oversight Committee may discuss or act on any item on this agenda, and as authorized by the Texas Open Meetings Act, Texas Government Code Section 551.001 et seq., may meet in closed session concerning any purpose permitted by the Act.

1. Call to Order
2. Roll Call/Excused Absences
3. Adoption of Minutes from the November 18, 2020, meeting Tab 1
4. Public Comment
5. Grantee Presentations Tab 2
6. Chief Executive Officer Report Tab 3
 - CEO Report Pursuant to Health & Safety Code § 102.260(c)
7. Chief Compliance Officer Report and Compliance Certification of Grant Award Process Tab 4
8. Chief Scientific Officer Report Tab 5
 - Grant Award Recommendations
9. Chief Prevention Officer Report Tab 6
 - FY 2022 Requests for Applications

10. Chief Product Development Officer Report Tab 7
 - FY 2022 Requests for Applications
11. Internal Auditor Report Tab 8
12. Scientific Research and Prevention Program Committee Appointments Tab 9
13. Amendments to 25 T.A.C. Chapters 702 and 703 Tab 10
 - Final Order Approving Amendments to Chapter 703
 - Proposed Amendments to Chapters 702 and 703
14. Chief Operating Officer Report Tab 11
15. Contract Approval for Search Firm Tab 12
16. Communications Report Tab 13
17. Subcommittee Business
18. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
19. Consultation with General Counsel
20. Future Meeting Dates and Agenda Items
21. Adjourn



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

**Oversight Committee Meeting Minutes
November 18, 2020**

NOTE: CPRIT conducted this meeting by videoconference in accordance with Governor Abbott's suspension of various provisions requiring government officials to be physically present at a specified meeting location. Unless the information is confidential, the reports, presentations, and grant award information referenced in the minutes are available in the "Oversight Committee Board Packet" section for the corresponding meeting date at <http://ocmeetings.cprit.texas.gov>.

Call to Order – Agenda Item 1

With a quorum present, Presiding Officer Dee Margo called the meeting to order at 9:01 a.m.

Roll Call/Excused Absences – Agenda Item 2

Committee Members Present

David Cummings, M.D.
Ambrosio Hernandez, M.D.
Donald (Dee) Margo
Will Montgomery
Mahendra Patel, M.D.
Cindy Barberio Payne
Bill Rice, M.D.
Craig Rosenfeld, M.D.

Adoption of Minutes from the August 19, 2020 Meeting – Agenda Item 3 – Tab 1

MOTION:

On a motion by Dr. Rice and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the minutes of the August 19, 2020, Oversight Committee meeting as presented.

Public Comment – Agenda Item 4

No member of the public requested to make public comment.

Resolution Honoring Angelos Angelou – Agenda Item 5, Tab 2

Presiding Officer Margo presented a resolution honoring former Oversight Committee member Angelos Angelou for his service to Texas and CPRIT. Mr. Angelou thanked the Board and staff.

MOTION:

On a motion by Dr. Patel and seconded by Dr. Hernandez, the Oversight Committee unanimously voted to approve the resolution.

Grantee Presentation – Agenda Item 6, Tab 2

Presiding Officer Margo recognized Chief Scientific Research Officer Dr. Jim Willson. Dr. Willson introduced Dr. Patrick Sung, CPRIT Scholar and Professor of Biochemistry and Structural Biology at The University of Texas Health Science Center at San Antonio. Dr. Sung provided a presentation on his CPRIT-funded project regarding DNA repair, chromosome stability, and cancer.

Presiding Officer Margo recognized Chief Product Development Officer Cindy WalkerPeach. Dr. WalkerPeach introduced Dr. Mei Wang, CEO and Co-Founder of CPRIT grantee Instapath Inc. Dr. Wang updated the Oversight Committee on Instapath's development of a rapid pathology evaluation system for biopsies. Instapath received a CPRIT SEED award in 2019 to support this project.

Chief Executive Officer Report – Agenda Item 7, Tab 3

Presiding Officer Margo recognized Mr. Roberts to present the Chief Executive Officer's Report. Mr. Roberts discussed the status of available grant funds and provided an update on COVID-19 related activities in the agency. He also gave a preview of the upcoming legislative session.

Chief Compliance Officer Report and Compliance Certification for the Proposed Grant Awards – Agenda Item 8, Tab 4

Presiding Officer Margo recognized Chief Compliance Officer Vince Burgess to present the Compliance Report and Compliance Certification of Grant Award Process. Mr. Burgess updated members on the compliance program activities for the past quarter.

With no questions on compliance activities, Mr. Burgess certified that the review process for the proposed academic research awards presented for the Oversight Committee's consideration complied with all applicable state and agency requirements. He noted that he included his written certification in the proposed award book at page 25.

Chief Scientific Officer Report and Grant Award Recommendations – Agenda Item 9, Tab 5

Presiding Officer Margo recognized Dr. Willson to present the academic research program update and award recommendations.

Dr. Willson referred members to page 5-3 in the meeting book and provided an overview of the outcome of applications reviewed in FY 2020 and other academic research grantee impact data.

He also presented proposed FY 22.1 RFAs for Oversight Committee consideration, referring members to page 5-1. The proposed RFAs included Individual Investigator Research Awards, Individual Investigator Research Awards for Computational Systems Biology of Cancer, Individual Investigator Research Awards for Cancer in Children and Adolescents, Individual Investigator Research Awards for Prevention and Early Detection and Individual Investigator Research Awards for Clinical Translation.

Following the RFA presentation, Dr. Willson laid out the proposed recruitment award

recommendations, which start on page 6 of the Proposed Grant Award book. The recommendations for FY 2021 recruitment cycles 21.1, 21.2 and 21.3 include 9 awards from 2 grant mechanisms totaling \$26,000,000.

Scientific Review Council and Program Integration Committee Recommendations for Recruitment Cycles FY 21.1, 21.2 and 21.3

Rank	App. ID	Mechanism	Candidate	Organization	Budget	Overall Score
1	RR210012	RFTFM	Furqan Fazal, Ph.D.	Baylor College of Medicine	\$2,000,000	1.0
2	RR210018	RFTFM	Guy Nir, Ph.D.	The University of Texas Medical Branch at Galveston	\$2,000,000	1.0
3	RR210016	RFTFM	Jihan Osborne, Ph.D.	The University of Texas Southwestern Medical Center	\$2,000,000	1.0
4	RR210005	RFTFM	Xiaoli Sun, Ph.D.	The University of Texas Health Science Center at San Antonio	\$2,000,000	1.0
5	RR210007	REI	Bissan Al-Lazikani, Ph.D.	The University of Texas M. D. Anderson Cancer Center	\$6,000,000	2.0
6	RR210013	RFTFM	Jeanine Van Nostrand, Ph.D.	Baylor College of Medicine	\$2,000,000	2.0
7	RR210006	REI	Peter Van Loo, Ph.D.	The University of Texas M. D. Anderson Cancer Center	\$6,000,000	2.0
8	RR210008	RFTFM	Pavan Bachireddy, M.D.	The University of Texas M. D. Anderson Cancer Center	\$2,000,000	2.0
9	RR210017	RFTFM	Mauro Di Pilato, Ph.D.	The University of Texas M. D. Anderson Cancer Center	\$2,000,000	2.0

REI- Recruitment of Established Investigators, RFTFM- Recruitment of First-Time Tenure Track Faculty Members

Conflict of Interest Notification

Presiding Officer Margo noted for the record that no Oversight Committee members reported conflicts of interest with any proposed academic research awards.

Academic Research Award Approval

Presiding Officer Margo called for a vote on the award recommendations.

MOTION:

On a motion made by Mr. Montgomery and seconded by Dr. Rice, the Oversight Committee members voted unanimously to approve the PIC’s recommendations for the two award slates: recruitment of first-time tenure track faculty members and recruitment of established investigators.

MOTION:

On a motion made by Dr. Rice and seconded by Mr. Montgomery, the Oversight Committee members voted unanimously to approve the delegation of contract negotiation authority to CPRIT's CEO and staff and authorized the CEO to sign the contracts on behalf of CPRIT.

Approval – Cycle 22.1 Requests for Applications

Presiding Officer Margo called for a vote on the proposed fiscal year 2022 Academic Research RFAs that CPRIT will release for the first cycle of fiscal year 2022.

MOTION:

On a motion made by Dr. Rice and seconded by Mr. Montgomery, the Oversight Committee members voted unanimously to approve the proposed fiscal year 2022, cycle 1 RFAs.

Chief Prevention Officer Report – Agenda Item 10, Tab 6

Presiding Officer Margo recognized Chief Prevention Officer Ramona Magid to provide an update on the prevention program. Ms. Magid gave an overview of the first cycle of grant applications for fiscal year 2021 and the RFAs that were recently issued for the second cycle. Ms. Magid highlighted the additional prevention program priority for fiscal year 2022 that the Oversight Committee's Prevention subcommittee recommended for approval.

Ms. Magid also gave a presentation on the impact of the COVID-19 pandemic on the number of cancer screenings and diagnostics provided by current CPRIT Prevention program grantees. Ms. Magid explained that CPRIT programs experienced an overall 40% decrease in the number of screenings and diagnostic tests as compared to the previous year. She highlighted the work that grantees are undertaking now to encourage the public to continue with their preventive health care.

An Oversight Committee member asked for clarification on the time covered by the presentation and the dip in numbers in the third quarter of 2019. Ms. Magid explained that the data varies between quarterly reporting periods, often reflecting the initiation or conclusion of various projects. After more discussion about data collection, an Oversight Committee member indicated that he would follow up with Ms. Magid after the meeting.

Chief Product Development Officer Report – Agenda Item 11, Tab 7

Presiding Officer Margo recognized Chief Product Development Officer Dr. Cindy WalkerPeach to present the Product Development Program update. Dr. WalkerPeach provided an update on the timeline and plan for the current fiscal year 2021 application cycle.

FY 2022 Program Priorities – Agenda Item 12, Tab 8

Presiding Officer Margo recognized Mr. Roberts to present the fiscal year 2022 program priorities. Mr. Roberts explained that the priorities are the same as the fiscal year 2021 priorities except for one addition to the prevention program priorities. He noted that each program subcommittee recommends approval of the proposed priorities.

MOTION:

On a motion made by Dr. Rice and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the fiscal year 2022 program priorities.

Internal Auditor Report – Agenda Item 12, Tab 9

Presiding Officer Margo recognized Dan Graves, a partner with Weaver & Tidwell, CPRIT’s internal audit contractor. Mr. Graves presented the internal audit status report, an audit advisory report on disaster recovery and business continuity planning, the internal audit report on board governance and the FY 2020 Annual Internal Audit Report. He noted that the State Auditor’s Office granted CPRIT a filing extension request to allow CPRIT to submit the fiscal year 2020 internal audit report after the Oversight Committee approved it at this meeting.

MOTION:

On a motion made by Mr. Montgomery and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the Disaster Recovery and Business Continuity Planning Audit Advisory Report and the Internal Audit Report over Governance.

MOTION:

On a motion made by Dr. Rice and seconded by Dr. Patel, the Oversight Committee unanimously voted to approve the FY 2020 Annual Internal Audit Report.

**Scientific Research and Prevention Program Committee Appointments – Item 14, Tab 10
Advisory Committee Appointments – Item 15, Tab 11**

Presiding Officer Margo recognized Mr. Roberts to take up agenda items 14 and 15 together. Mr. Roberts presented his eight appointments to the Scientific Research and Prevention Program Committees and the Presiding Officer’s appointment to the Prevention Advisory Committee. Mr. Roberts informed members of two new University Advisory Committee members, Dr. Subhash Chauhan (The University of Texas Rio Grande Valley) and Dr. Giulio F. Draetta (The University of Texas M.D. Anderson Cancer Center).

MOTION:

On a motion made by Dr. Rice and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve Mr. Roberts’ eight appointments to CPRIT’s Scientific Research and Prevention Program Committees.

MOTION:

On a motion made by Dr. Rice and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve Dr. Abbey Berenson’s appointment to the Prevention Advisory Committee.

Amendments to 25 T.A.C. Chapter 703 – Item 16, Tab 12

Presiding Officer Margo recognized CPRIT assistant general counsel Cameron Eckel to present two proposed rule changes to Chapter 703. Ms. Eckel reviewed the proposed rule changes relating to

publishing the minimum level of effort requirements for certain key grantee personnel in a request for applications and the allowability of professional association fees paid by a grantee.

MOTION:

On a motion by Dr. Patel and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the publication of the proposed changes to Texas Administrative Code Chapter 703 in the *Texas Register*.

Chief Operating Officer Report – Agenda Item 17, Tab 13

Presiding Officer Margo recognized Chief Operating Officer Heidi McConnell to present the Chief Operating Officer’s Report. Ms. McConnell reported on the FY 2020 fourth quarter operating budget, performance measures, and debt issuance and highlighted that CPRIT received more than \$947,000 in revenue sharing payments in fiscal year 2020.

Communications Report – Agenda Item 18, Tab 14

Presiding Officer Margo recognized Senior Communications Specialist Chris Cutrone to present the communications update. In his presentation Mr. Cutrone highlighted the launch of a page featuring projects CPRIT funds in liver cancer.

Subcommittee Business – Agenda Item 19

Compliance Investigation Pursuant to Health & Safety Code § 102.2631 – Agenda Item 20

Consultation with General Counsel – Agenda Item 21

Future Meeting Dates and Agenda Items – Agenda Item 22

The Oversight Committee did not take up these items.

Adjournment – Agenda Item 23

MOTION:

There being no further business, the Oversight Committee unanimously voted to approve a motion to adjourn made by Presiding Officer Margo and seconded by Mr. Montgomery.

Meeting adjourned at 11:08 a.m.

Signature

Date

Abbey B. Berenson, MD, PhD



Professor, Departments of Obstetrics & Gynecology and Pediatrics

Director, Center for Interdisciplinary Research in Women's Health

The Ruth Hartgraves MD Chair in Obstetrics & Gynecology

Dr. Berenson is a senior clinical researcher, gynecologist, and mentor, with an international reputation for studies of health issues among

reproductive-aged women. In 2002 UTMB selected her as the first female director of a research center, and as such, she is the founding Director of the UTMB Center for Interdisciplinary Research in Women's Health (CIRWH). She developed CIRWH's infrastructure to promote involvement and success of junior faculty from a number of departments. During the past 25 years, Dr. Berenson has dedicated substantial effort to train the next generation of researchers, mentoring 21 postdoctoral fellows and 17 assistant professors from a broad array of disciplines related to healthcare of women. She has worked with early career investigators from obstetrics and gynecology, rehabilitation sciences, preventive medicine, family medicine, surgery, oncology, psychology, psychiatry, nutritional sciences, and epidemiology. Mentees include 11 MDs and 30 PhDs, the majority of whom have remained in academic research and have obtained funding as principal investigators on their own external awards.

Dr. Berenson has maintained extramural federal and state grant support since 1994. Her studies include approaches supported by multidisciplinary teams and have resulted in over 230 peer-reviewed publications in high impact journals. Areas of research include: Comparative effectiveness studies among diverse populations of young women including: 1) contraception practices, methods, and effects (clinical); 2) interventions directed at cervical cancer prevention (clinical); and 3) epidemiologic studies on prevalence and correlates of infection with human papillomavirus. Sponsors include the National Institutes of Health (NIH), Health Resources &

Services Administration (HRSA), Department of Defense (DoD), several private foundations, and the Cancer Prevention & Research Institute of Texas (CPRIT). NIH recognized her successful mentoring history by awarding her support from a K24 for the 10-year maximum. The K24 mechanism provided protected time to devote to mentoring activities.

In addition, Dr. Berenson has served on the national level as a board examiner for the American Board of Obstetrics and Gynecology. She has also served on numerous committees for American College of Obstetricians and Gynecologists, the board of directors for the American Gynecological and Obstetrical Society and was the first female president of the Central Association of Obstetricians & Gynecologists. In addition, she was a panel member for the CDC's US Guidelines for Contraceptive Management and has been a member of several Scientific Review Groups for the National Institutes of Health.

Increasing HPV vaccination rates in low-income patients

Abbey Berenson MD, PhD, MMS

Professor and Director, Center for Interdisciplinary Research in Women's Health

University of Texas Medical Branch

HPV-related cancers in US

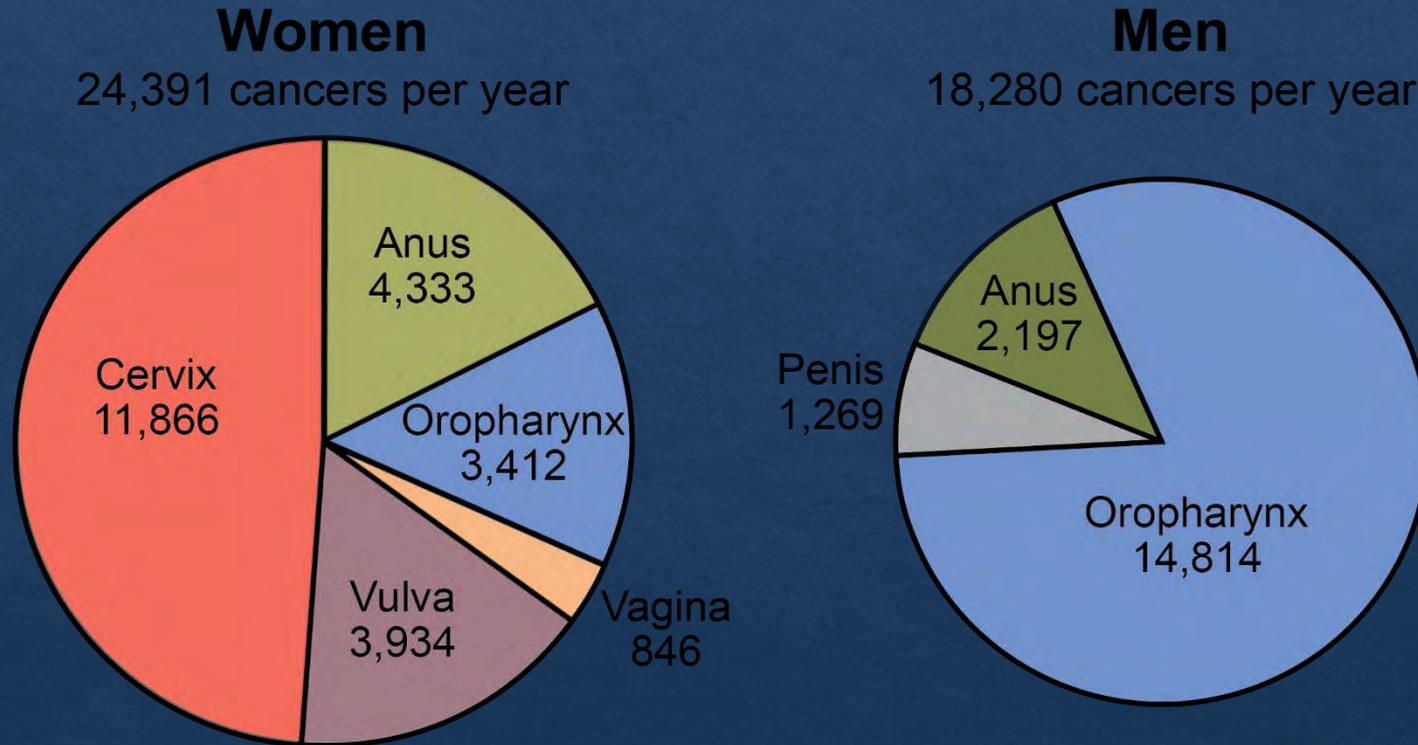


Image recreated from data presented in Centers for Disease Control and Prevention. USCS Data brief, no. 4, 2018.

HPV vaccine approved in 2006

- Has potential to markedly reduce occurrence of 6 different types of cancer
- 2-3 doses given 6-12 months
- Recommended at 11-12 years old
 - Can be given as young as 9 years old
 - Catch-up vaccination first allowed up to age 26 and now 45

Uptake very slow in US

CDC: 80% of girls and boys need to complete all doses to eliminate 4vHPV types in population

	2018	
	1 dose	All doses
13–17 yo	68%	51%
18–26 yo	40%	21%

Baseline rates very low among UTMB's low-income patients

HPV vaccine interventions

- Many reported interventions have had poor success rates.
- Multicomponent interventions are most successful.
- Interventions demonstrated to work include those which use patient navigators, provider education, and patient reminders.

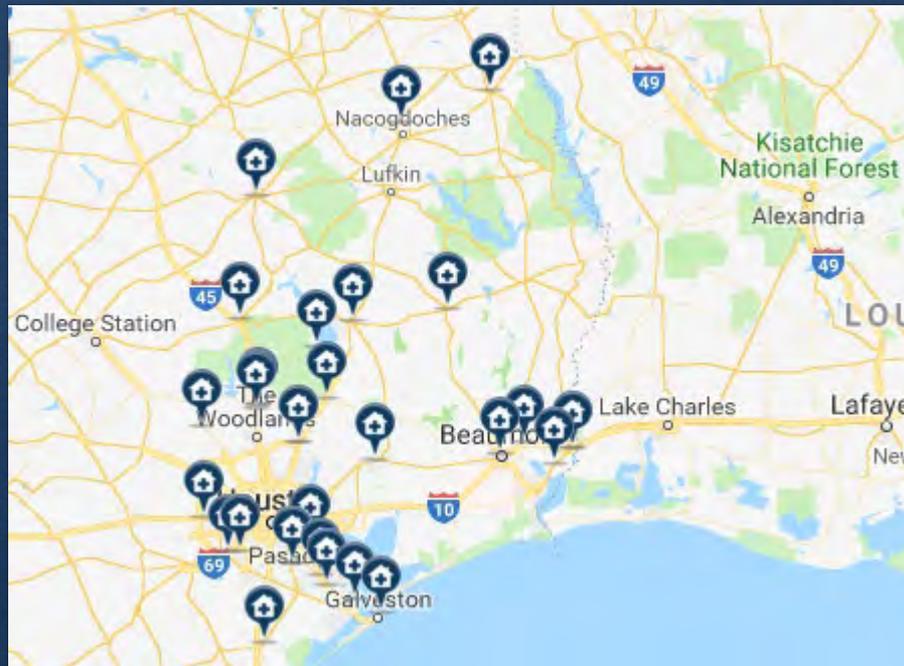
Evidence-based interventions

- Patient navigation
 - Patients need accurate information about the vaccine
 - Patients need help remembering appointments and rescheduling missed appointments
- Provider education increases number of providers who recommend vaccine and demonstrates how to do this
- Additional vaccination sites
 - Can be difficult for patients to find vaccination site
 - May not be able to get vaccine during existing visits
- Financial assistance due to high cost of vaccine

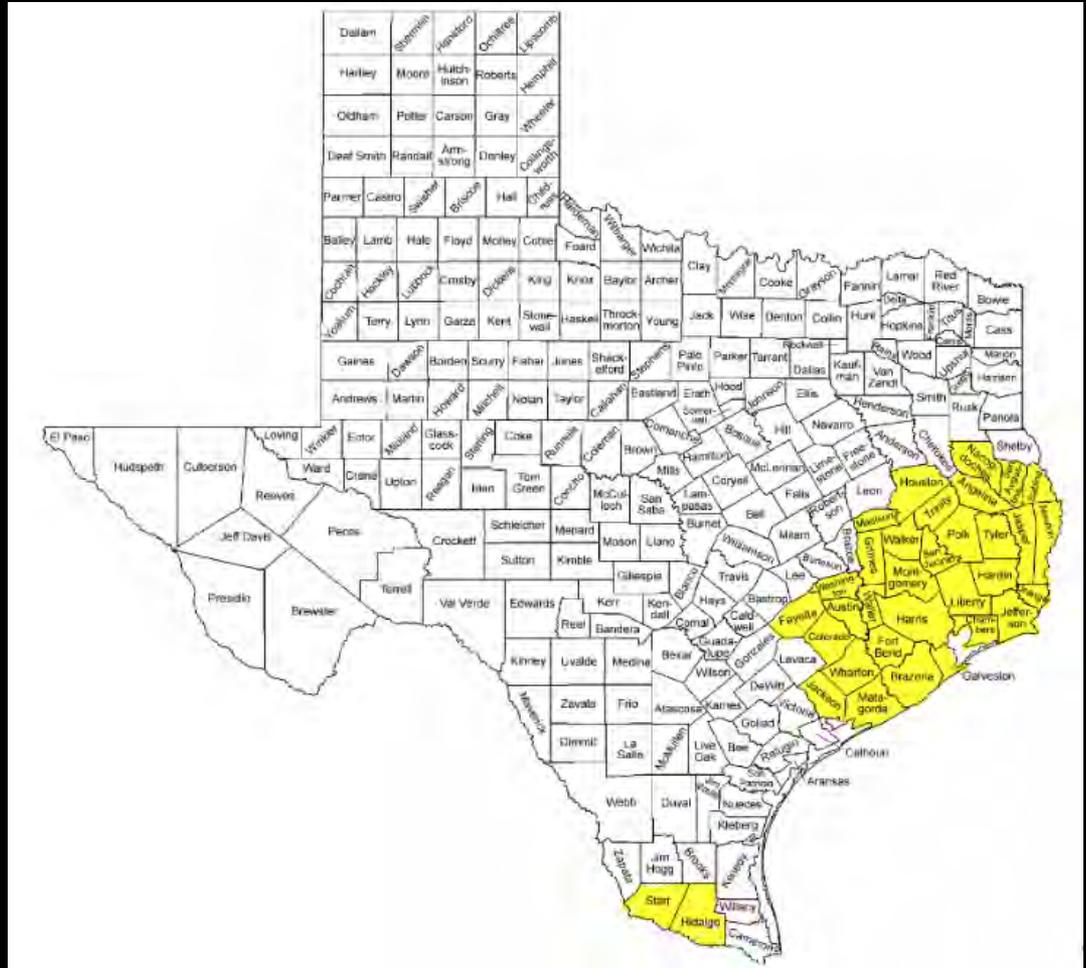
Prevention projects 2012-2021

1. Postpartum unit
2. Pedi/adolescent primary care and subspecialty clinics
3. East Texas reproductive health clinics
4. Rio Grande Valley reproductive health clinic

UTMB Clinics across S Texas



Area encompasses 11 Senate and 29 House districts of the Texas legislature



Race/ethnicity of participants

	Hispanic	White	Black
Postpartum unit	67%	20%	11%
Pedi/Adolescent clinics	37%	31%	31%
East Texas	31%	28%	39%
Rio Grande Valley	81%	13%	6%

Patient income in regional clinics

- Over 75% report family income under \$30,000
- Only 15% have private insurance
- CPRIT funding allowed us to offer vaccine at no cost

Intervention:

Postpartum vaccination

- Women hospitalized at least 24 hours after delivery
 - Ample time for patient education
 - Postpartum administration of Rubella vaccine has been done for decades
- Follow-up doses coordinated with postpartum appointments or newborn checkups

Postpartum intervention: Cycle 1 (2012)

- Limited to women ≤ 26 yo from 1 county
- 1204 received 1st dose on pp unit
- Administered 3531 total doses
- Initiation rate increased from 25% to 81%
- Completion rate: 94%
- 563 professionals attended HPV lectures

Postpartum intervention: Cycle 2

- Expanded to ALL pp women at UTMB ≤ 26 yo
- Expanded from 1 to 29 counties:
 - 5 MUA and 17 MUA/rural
- 2284 received 1st dose postpartum
- Administered 6427 total doses
- Completion rate 86%
- 722 professionals attended HPV lectures

System change: Instituted standing orders on pp unit for HPV vaccination

Interviews with providers

- Method accepted and integrated into SOC
 - “In the beginning, it was like ‘Golly, we gotta give another shot?’ ...we just got something extra to do... We have been doing it for a couple of years... It’s in our routine.
 - --RN, OB/GYN, on postpartum unit

Postpartum intervention: Cycle 3 (2020-2023)

- Women ≤ 45 years old who deliver at UTMB from all counties PLUS
- Postpartum patients in Rio Grande Valley receiving care at UTRGV's resident clinic
- All personnel from UTMB and UTRGV meet monthly

Pedi/adolescent clinic intervention

- Males and females 11-17 years of age seen in UTMB's pediatric clinics
- Included subspecialists who did not routinely prescribe vaccines
- On site patient navigators provided counseling and addressed questions
- Hired nurse to help with increased workload
- Increased supply obtained from Vaccine for Children Program

Education provided

- Educated subspecialists of need to prescribe vaccine
- Educated clinic staff on need to keep vaccine in stock
- Educated staff and parents of need to:
 - ❖ vaccinate the child that day
 - ❖ make follow up appointments before leaving clinic
 - ❖ schedule appointments for other siblings

Pedi/adolescent clinic Intervention: Cycle 1

- Limited to 2 counties (Galveston, Brazoria)
- Initiation rate increased from 36% to 67%
- Vaccinated 1297 females and 1388 males
- Delivered 5745 doses
- Completion rate 93%
- 452 professionals attended HPV lecture
- 101 parents participated in post-project interviews

Interviews with parents

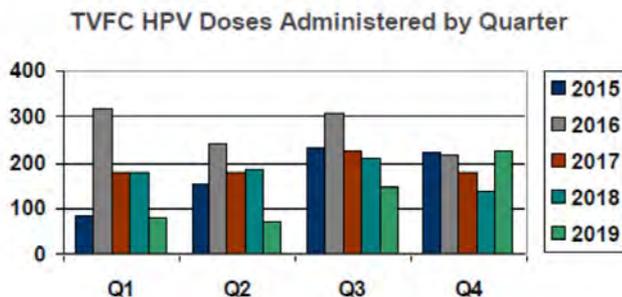
- *“When I went in after the first appointment, they made sure to make the next appointments for me so that I wouldn’t forget. So they made it easy for me.”*
- *“Now we get texts reminding us so that’s a really good idea whoever came up with that.”*

Pedi/adolescent clinic intervention: Cycle 2

- In progress (Year 2)
- Expanded from 2 to 23 counties
- Have vaccinated 957 females and 1080 males
- Delivered 4008 vaccine doses
- 522 professionals attended HPV lecture

Adolescent Vaccine Doses Administered

TVFC Vaccine	2018 Jan-Dec	2019 Jan-Dec	Percent Change (%)
HPV	715	520	-27
Tdap	290	182	-37
MCV4	347	395	14
TVFC Eligible Patient Estimate (7-18 years old)	180	1,420	689



TVFC Provider Report on Adolescent Vaccines

UTMB Pediatric Health-Bay Colony
TVFC PIN: TX061514

Ratio of Tdap doses to HPV doses administered:

1 : 2.9

How Do You Compare?

224
IN THE STATE
(2884 providers)

1
IN THE COUNTY
(29 providers)

Comparable Tdap to HPV Doses

1 : 1.5
TEXAS

1 : 1.6
GALVESTON COUNTY

Vaccine administration performance:

Excellent

EXCELLENT ($\geq 1 : 2.0$)
FAIR (1 : 1.5 - 1 : 1.9)
POOR ($\leq 1 : 1.4$)

East Texas intervention

- Cervical cancer rates higher in east Texas than rest of state
- Significant percentage of population opposes vaccinations
- Baseline HPV vaccination initiation rates 14% among UTMB patients visiting clinics in Jefferson and Orange counties

East Texas intervention: Cycle 1

Initiation rate increased from 14% to 60%

Completion rate 70%

Administered 4029 doses to males and females

383 professionals attended lecture on HPV vaccination

50 patients completed qualitative interviews

East Texas intervention: Cycle 2

- Began during pandemic on 3/1/20
- Expanded from 2 to 13 counties
- In first 9 months, we have:
 - Vaccinated 525 women
 - Delivered 872 doses
 - Educated 158 professionals

Rio Grande Valley intervention

- UTMB operates reproductive health clinic in McAllen, Texas
- Clinic did not stock the HPV vaccine or have a refrigerator to do so
- Baseline data revealed very few patients 18-26 yo had received even 1 vaccine dose

Rio Grande Valley Project: Cycle 1

- In progress (2018-2021)
- Purchased refrigerator and vaccine now in stock
- Vaccinated 1149 women
- Administered 2598 doses
- 473 professionals attended HPV lecture

Dissemination

- Outcomes have been disseminated throughout Texas and across US
- Total for all projects:
 - ❖ 23 presentations at meetings
 - ❖ 9 peer-reviewed publications
 - ❖ 12 invited lectures

Peer-reviewed publications

1. Berenson AB, Rahman M, Hirth JM, Rupp RE, Sarpong KO. A brief educational intervention increases providers' human papillomavirus vaccine knowledge. *Hum Vaccin Immunother.* 2015;11:1331-6. PMID: 25945895. PMCID: 4514429. [From CPRIT PP120150 – PPW-1]
2. Berenson AB, Rahman M, Hirth JM, Rupp RE, Sarpong KO. A human papillomavirus vaccination program for low-income postpartum women. *Am J Obstet Gynecol.* 2016;215(3):318.e1-9. PMID: 26899907; PMCID: PMC4988928. [From CPRIT PP120150 – PPW-1]
3. Gross TT, Rahman M, M Wright A, Hirth JM, Sarpong KO, Rupp RE, D Barrett A, Berenson AB. Implementation of a postpartum HPV vaccination program in a Southeast Texas hospital: A qualitative study evaluating health care provider acceptance. *Matern Child Health J.* 2016;20(Suppl 1):154-163. PMCID: PMC5121006. [From CPRIT PP120150 – PPW-1]
4. Berenson AB, Hirth JM, Fuchs EL; Multidisciplinary Translation Team on Reproductive Women's Health. US medical students' willingness to offer the HPV vaccine by vaccination status. *Vaccine.* 2017;35(9):1212-1215. PMID: 28161418; PMCID: PMC5364799. [From CPRIT PP150004 – PEDI-1]
5. Berenson AB, Rupp R, Dinehart EE, Cofie LE, Kuo YF, Hirth JM. Achieving high HPV vaccine completion rates in a pediatric clinic population. *Hum Vaccin Immunother.* 2019;15 (7-8):1562-1569. PMID: 30299220. PMCID: PMC6746521. [From CPRIT PP150004 – PEDI-1]
6. Hirth JM, Berenson AB, Cofie LE, Matsushita L, Kuo YF, Rupp RE. Caregiver acceptance of a patient navigation program to increase human papillomavirus vaccination in pediatric clinics: a qualitative program evaluation. *Hum Vaccin Immunother.* 2019;15(7-8):1585-1591. PMID: 30829116; PMCID: PMC6746533. [From CPRIT 150004 – PEDI-1]
7. Berenson AB, Hirth JM, Fuchs EL, Chang M, Rupp RE. An educational intervention to improve attitudes regarding HPV vaccination and comfort with counseling among US medical students. *Hum Vaccin Immunother.* 2020 May 3;16(5):1139-1144 PMID: 31809635. PMCID: PMC7227689 [From CPRIT PP160010 -- GT-1 and PP180012 – RGV-1]
8. Berenson AB, Hirth JM, Kuo YF, Rupp RE. Quantitative and qualitative assessment of an all-inclusive postpartum human papillomavirus vaccination program. *Am J Obstet Gynecol.* 2020 Nov 25:S0002-9378(20)31332-6. Epub ahead of print. [From PP120150 – PPW-1 and PP160058 – PPW-2]
9. Berenson AB, Hirth JM, Chang M, Kuo YF, Richard P, Jones DL. A brief educational intervention can improve nursing students' knowledge of the human papillomavirus vaccine and readiness to counsel. *Hum Vaccin Immunother.* In Press Dec 2020 [From PP180012 – RGV-1, PP160010 – GT-1, PP190004 – PEDI-2]

Lessons learned from projects

- Implementing new interventions in healthcare settings is difficult and time consuming.
- Success requires careful planning, frequent communication, and hard work.
- Need to support everyone -- clinic and hospital personnel, providers, and patients.
- Broad-based provider education important for sustainability.
- External funding makes a difference!

Prevention projects led to an important research question

- Observed that many patients required extensive support to complete all 3 doses
- Much easier for adolescents ≤ 14 years old to complete series as they need only 2 doses according to CDC guidelines
- No randomized, controlled trials conducted examining efficacy of 2 doses among boys and girls > 14 years of age

Research study

- Developed study to compare immune response after 2 vs. 3 doses among males and females over 14 years of age.
- Recruitment began in 2019
- Study continued to follow patients during Stay-At-Home orders in 2020
- Recruitment restarted after Stay-At-Home orders ended
- Have already recruited >350 males and females

Thank you

- The Cancer Prevention Research Institute of Texas
- UTMB hospitals and clinics
- The patient navigators, research nurses, managers, collaborators, and others who have contributed to the success of these projects





Dr. Michael A. Curran
Founder and SAB Head, ImmunoGenesis

Dr. Michael Curran is an Associate Professor of Immunology at the MD Anderson Cancer Center in Houston Texas and co-Scientific Director of the Oncology Research for Biologics and Immunotherapy Translation (ORBIT) program coordinating development and production of clinical immunotherapeutic antibodies. Dr. Curran received the Ph.D. degree from Stanford University training in the laboratory of Dr. Gary Nolan where he was awarded the McDevitt prize for the best graduate thesis in his year. Dr. Curran was the first recipient of the prestigious American Cancer Society Levy Fellowship to fund his post-doctoral studies in the lab of Dr. James P. Allison. While pursuing his postdoctoral studies at Memorial Sloan-Kettering Cancer Center, Dr. Curran published several influential manuscripts describing how T cell co-stimulatory pathways could be modulated, in tandem, to mediate immunologic rejection of melanomas in mice. Dr. Curran described how combination blockade of the T cell co-inhibitory receptors CTLA-4 and PD-1 promoted the rejection of most murine melanomas. This work supported the launch of a Phase I clinical trial in which greater than 50% of metastatic melanoma patients experienced objective clinical responses – a result so unprecedented that this became the first FDA-approved immunotherapy combination. In addition, his subsequent immunologic studies of 4-1BB agonist antibodies earned him the Society for the Immunotherapy of Cancer’s prestigious Presidential Award. The Curran Lab seeks to discover the underlying mechanisms of immune resistance in the “coldest” tumors, pancreatic and prostate adenocarcinoma and glioblastoma, so that rational therapeutic interventions can be developed to restore T cell infiltration and sensitivity to T cell checkpoint blockade.



James A. Barlow
President & CEO, ImmunoGenesis

Jim Barlow became the CEO of ImmunoGenesis in April 2020. Prior to joining ImmunoGenesis, Jim was Vice President of Operations and Business Development for Geneos Therapeutics. Jim played an integral role in the company formation of Geneos, a personalized neoantigen-targeting cancer vaccine company that is a spin-off from Inovio Pharmaceuticals. Jim was one of 2 initial employees, helped build-out the management team and established all key operational aspects of the company. He also led the tumor prioritization efforts resulting in the design and initiation of the company’s first clinical trial less than 9 months after obtaining Series A financing.

Before joining Geneos, Jim drove the development of Inovio’s Immuno-Oncology (IO) product strategy. In this effort, he led a cross-functional team across Commercial, Clinical, Product Development, R&D and Business Development to establish a set of key strategic principles. Jim drove the product prioritization efforts based on these principles, established the IO Advisory Panel, and drove KOL and pharma partner interactions to position the company to embark on major clinical programs across four tumor types of interest. These programs are evaluating combination regimens of Inovio’s cancer immunotherapies with PD-(L)1 inhibitors from 3 different pharma partners – Jim drove the establishment of two of these three partnerships as well as a clinical partnership with the Parker Institute for Cancer Immunotherapy.

Prior to Inovio, Jim was at Bristol-Myers Squibb where he was the Payer Marketing Lead for YERVOY®, the pioneering cancer immunotherapy whose approval set off the current wave of immunotherapy development in Oncology. Given the “First in Class” nature of the product and premium price associated with it, Jim created a number of innovative programs to optimize market access. While at BMS, Jim also worked on the overall IO franchise commercial strategy including the development of communication planning for the groundbreaking immunotherapy, OPDIVO®. Prior to BMS, Jim spent 8 years at Merck working in commercial leadership roles with increasing responsibility for the Oncology franchise.

Jim received a MBA (strategy and marketing) with honors from the Tepper School of Business at Carnegie Mellon University. He was awarded the Dean’s Scholarship from Tepper. Jim received his Bachelor of Arts in Math and Economics from Colgate University where he was awarded the Alumni Memorial Scholarship and he graduated Summa Cum Laude.



Presentation to The CPRIT Oversight Committee

February 2021



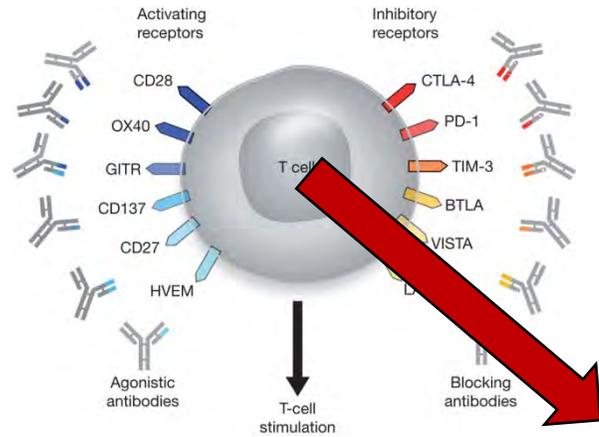
Scientific Background

Dr. Michael A. Curran, Founder

Immunotherapy continues to transform clinical oncology



T Cell Checkpoint Modulation

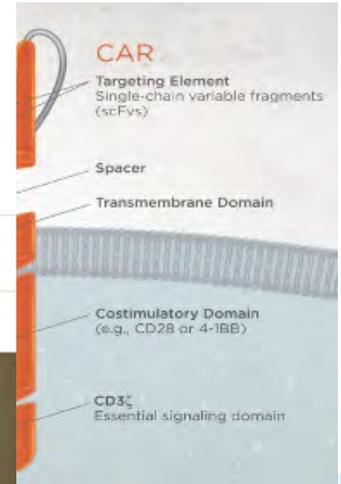


Jimmy Carter says he no longer needs cancer drug treatment

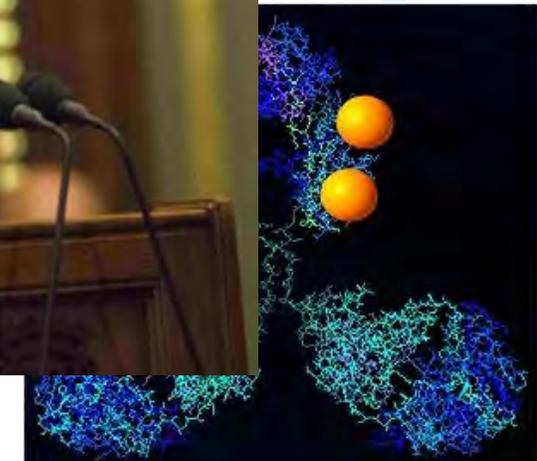
AP By KATHLEEN FOODY
March 6, 2016 6:47 PM



optive Transfer

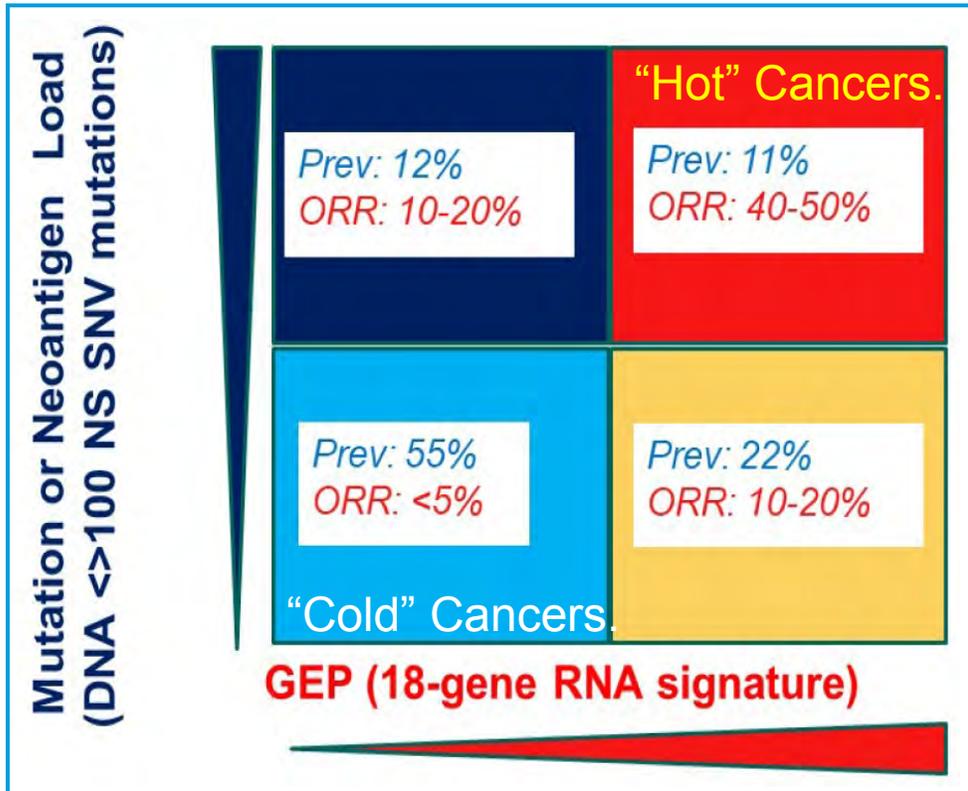


odies and ADCs



Checkpoint Immunotherapy Still Fails Most Patients

Current PD-1/PD-L1 inhibitors only work in “Hot” Cancers where the overall response rate (ORR) is 40-50%; **Little effect elsewhere**



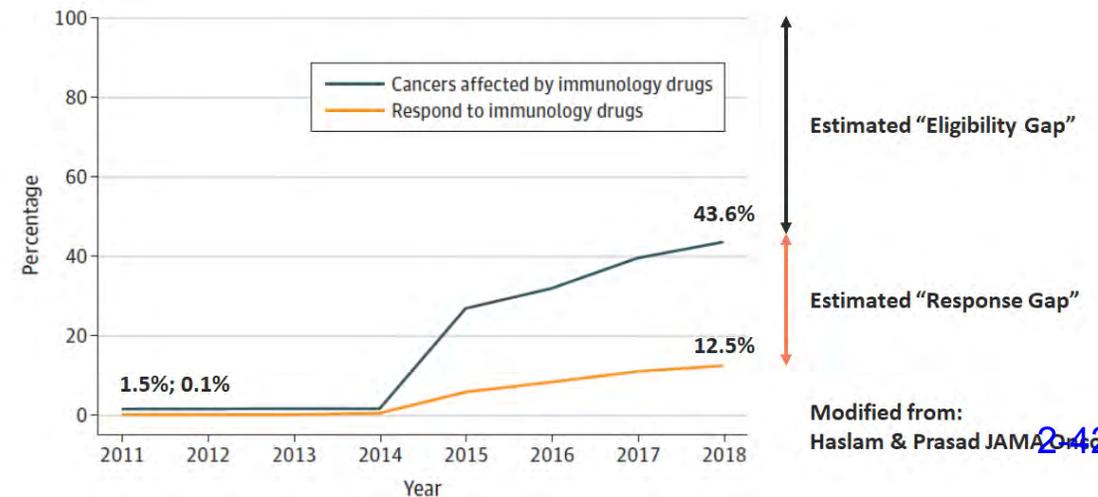
Seiwert, T., and Kaufman D.R. JCO.2018.36.5_suppl.25 *Journal of Clinical Oncology* 36, 2018.

Unmet Clinical Need

Only a minority (~45%) of cancer patients are eligible to receive a PD(L)-1 antibody, and $\leq 15\%$ of those achieve RECIST PR/CR.

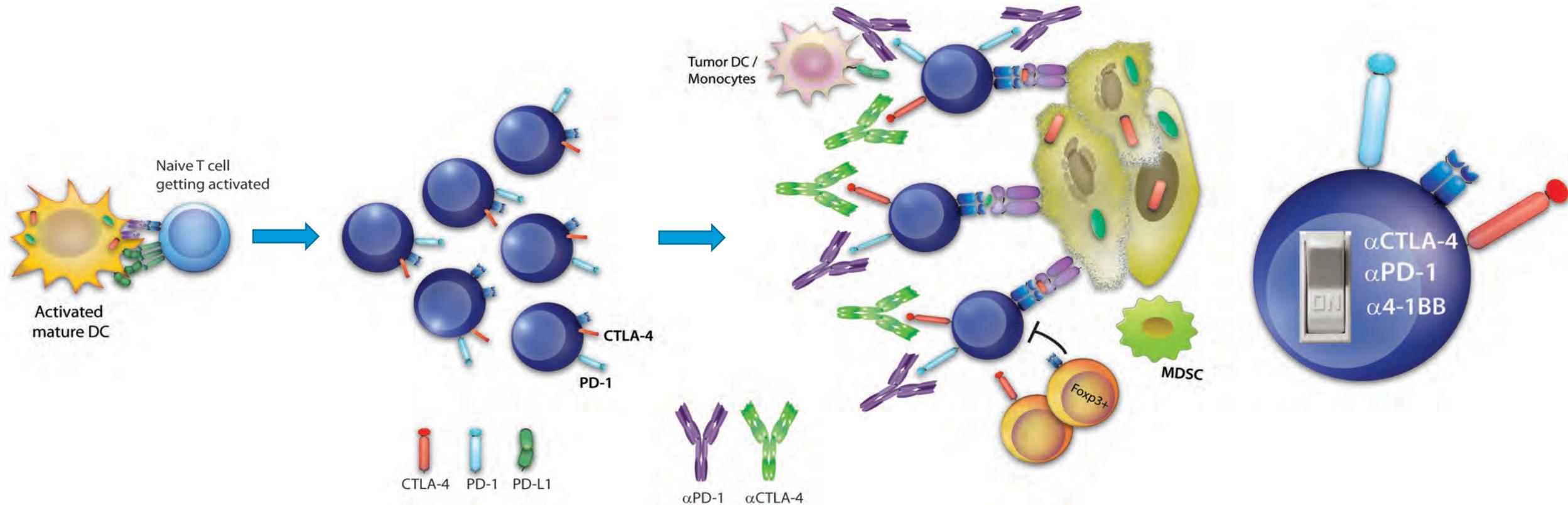
Haslam, A., and Prasad, V. *JAMA Netw Open*. 2019;2(5):e192535, 2020.

Figure 1. Percentage of US Patients With Cancer Who May Benefit From and Respond to Checkpoint Inhibitor Immunology Drugs (2011-2018)

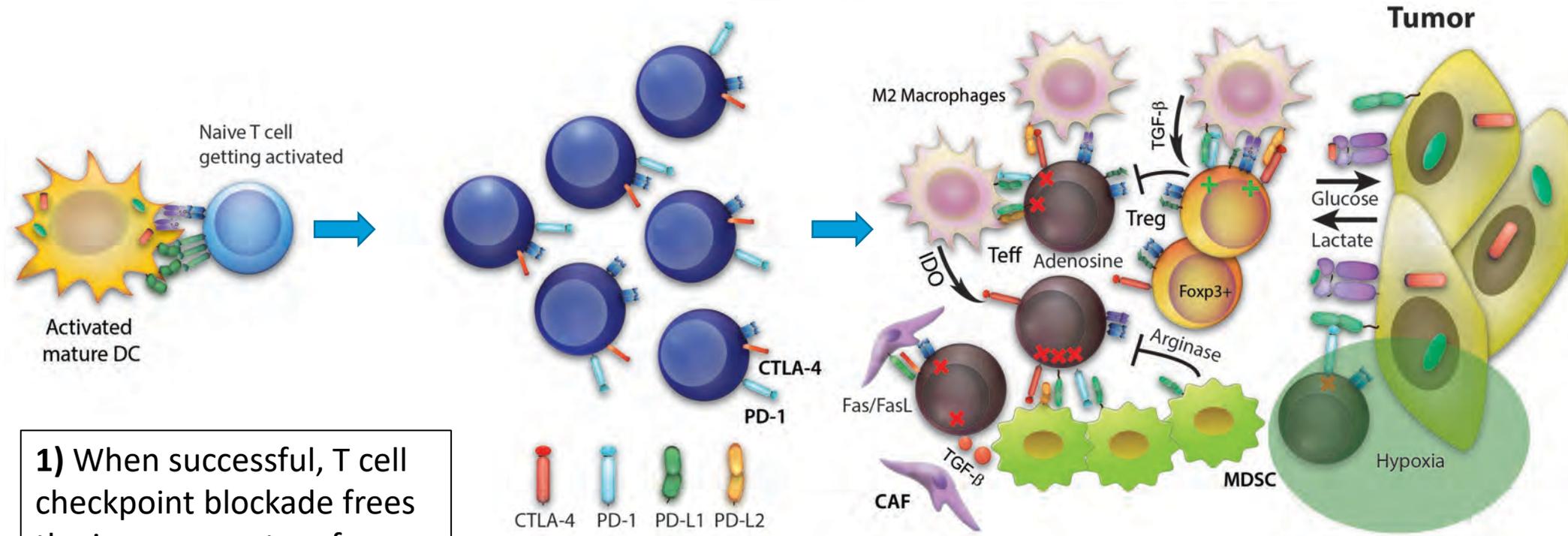


Modified from:
Haslam & Prasad *JAMA Oncology*, 2019

How do immune checkpoint antibodies (e.g. α PD-1) treat cancer?



Extrinsic suppression can be dominant over T cell checkpoint blockade.



1) When successful, T cell checkpoint blockade frees the immune system from repression in the tumor eliciting durable regression of even widespread cancer.

Grant ID: RP190218
Title: Deciphering the underlying biology and translational relevance of PD-L2

Grant ID: RP170399
Title: Elimination of hypoxia sensitizes resistant solid tumors to immunotherapy

2) Multiple mechanisms of immune suppression can repress T cells and prevent tumor regression even in the presence of checkpoint blocking antibodies.

PD-L2 is a Critical Regulator of Human Tumor Immunity

Biology of Human Tumors

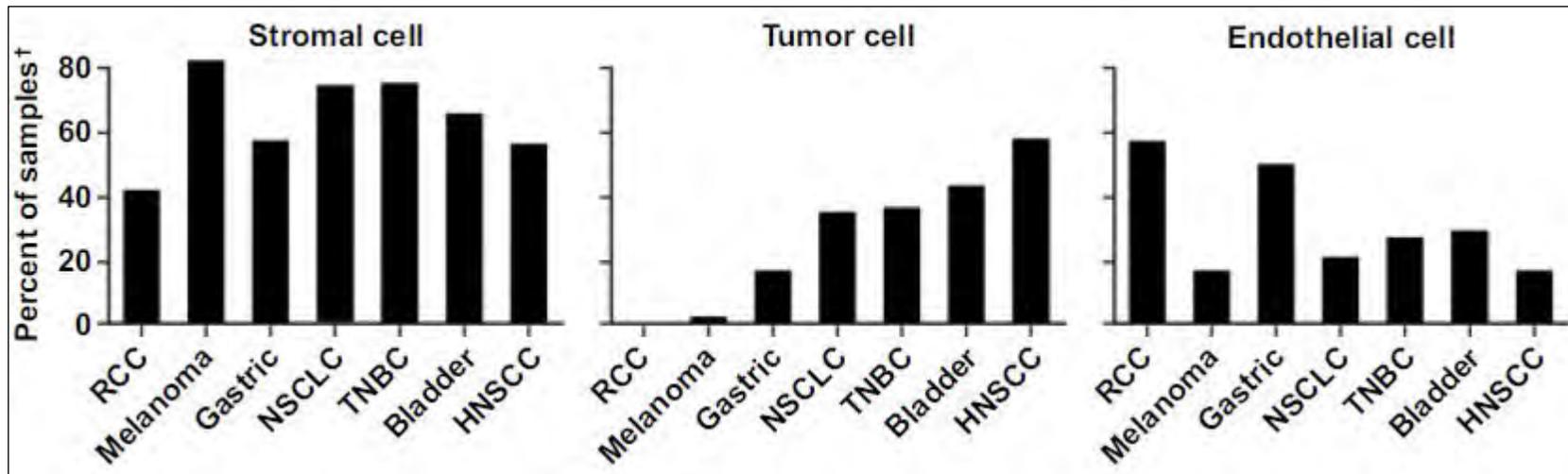
Clinical
Cancer
Research

PD-L2 Expression in Human Tumors: Relevance to Anti-PD-1 Therapy in Cancer

Jennifer H. Yearley¹, Christopher Gibson², Ni Yu¹, Christina Moon¹, Erin Murphy¹, Jonathan Juco¹, Jared Lunceford¹, Jonathan Cheng¹, Laura Q.M. Chow³, Tanguy Y. Seiwert⁴, Masahisa Handa¹, Joanne E. Tomassini¹, and Terrill McClanahan¹



PD-L2 Expression : Human Cancer



- 1) PD-L2 is widely expressed in the stroma, tumor, and endothelium of many cancers.
- 2) PD-L1 and PD-L2 expression are often correlated, yet either can dominate.
- 3) PD-L2 sometimes more strongly predicts response to PD-1 blockade than PD-L1.

Blocking both PD-L1/B7-1 in addition to PD-1 improves anti-tumor immunity



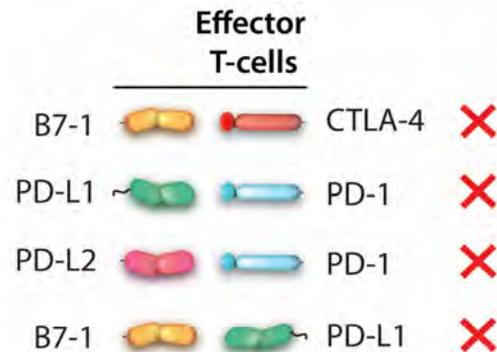
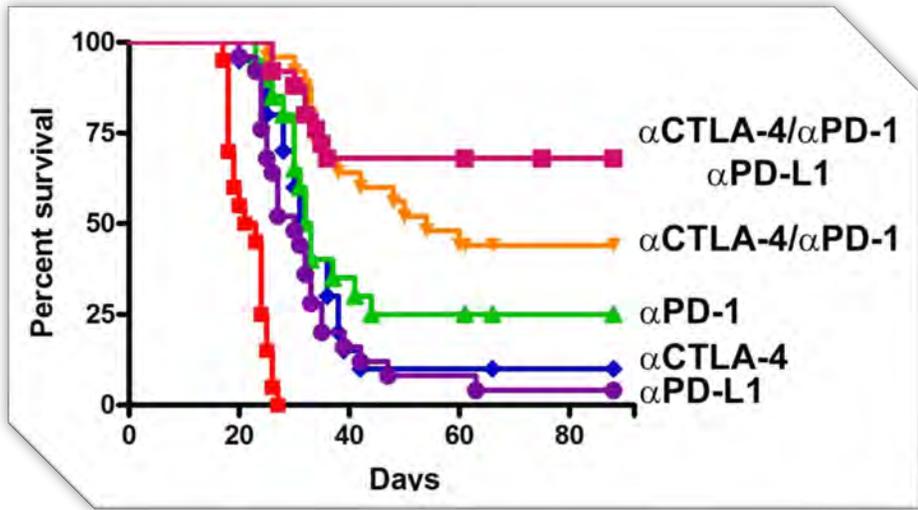
PNAS

PD-1 and CTLA-4 combination blockade expands infiltrating T cells and reduces regulatory T and myeloid cells within B16 melanoma tumors

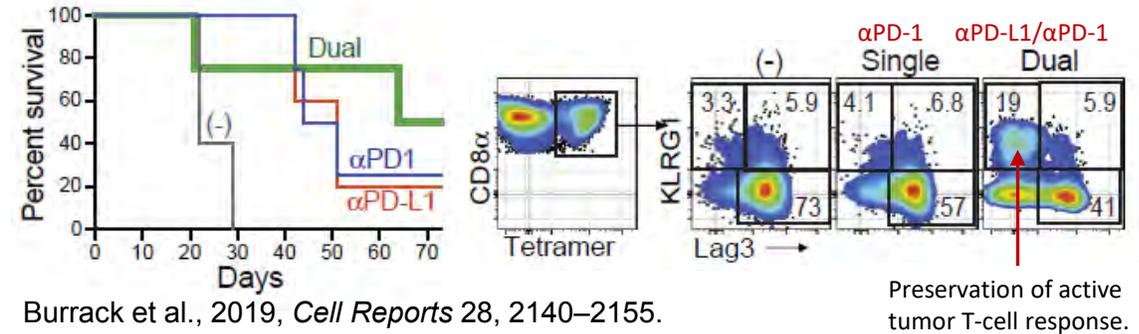
Michael A. Curran^a, Welby Montalvo^b, Hideo Yagita^b, and James P. Allison^{a,1}

^aHoward Hughes Medical Institute, Department of Immunology, Memorial Sloan-Kettering Cancer Center, New York, NY 10065; and ^bDepartment of Immunology, Juntendo University School of Medicine, 2-1-1 Hongo, Bunkyo-ku, Tokyo 113-8421, Japan

Contributed by James P. Allison, January 19, 2010 (sent for review December 17, 2009)

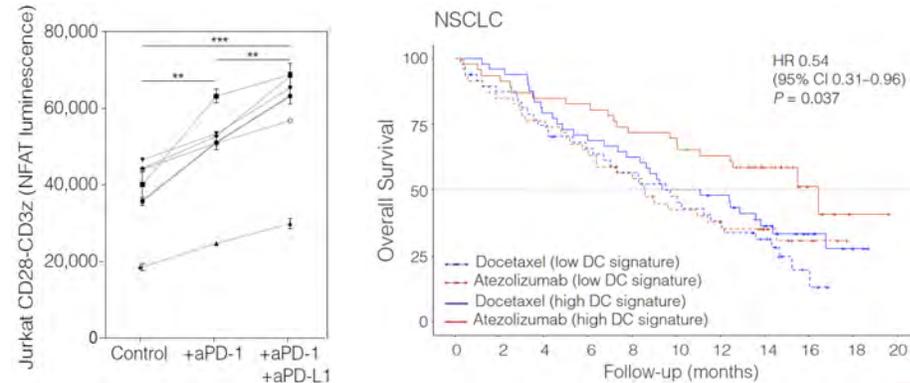


PD-L1 : B7-1 blockade optimizes murine tumor immunity



Burrack et al., 2019, *Cell Reports* 28, 2140–2155.

Patients with tumor DC benefit from PD-L1 : B7-1 blockade.



DC-high patients get extra benefit from PD-L1 blockade due to enhanced priming.

Mayoux et. Al., *Sci Transl Med.* 2020 Mar 11;12(534):eaav7431.

Combination αPD-1/αPD-L1 blockade is safe and effective.

Study #2016-0529

A Phase I, Open-Label, Multi-Center Dose Escalation Study of FAZ053 as Single Agent and in Combination with PDR001 in Adult Patients with Advanced Malignancies

FAZ053 = αPD-L1
PDR001 = αPD-1

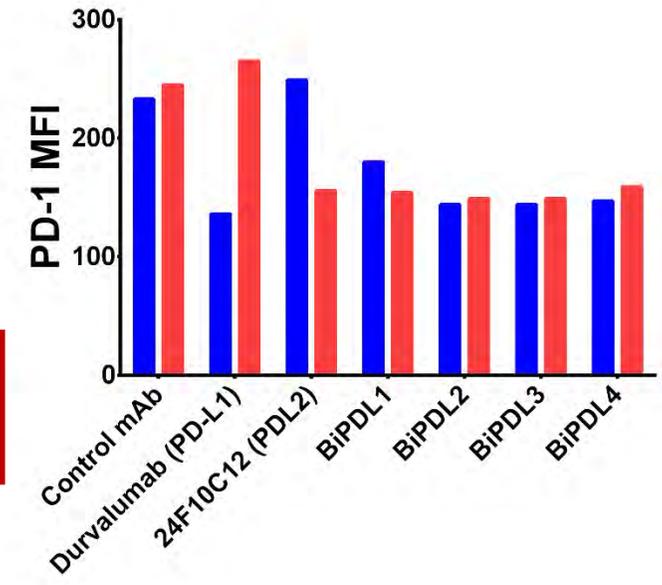
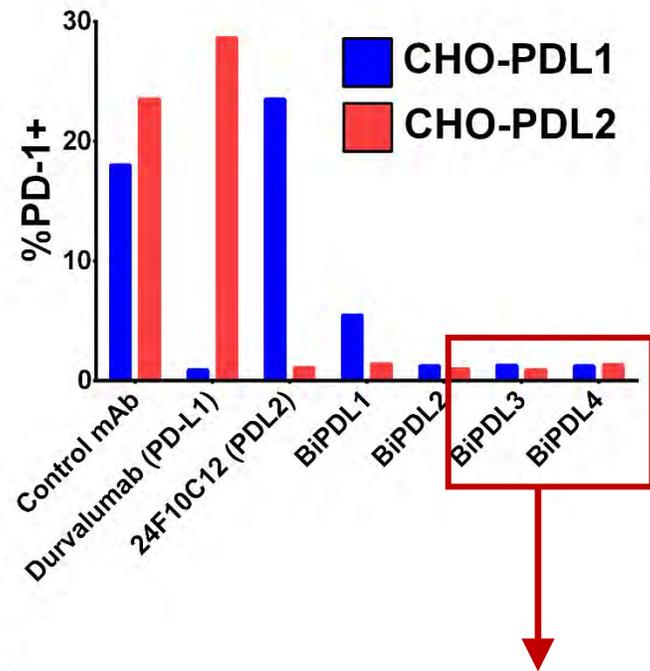
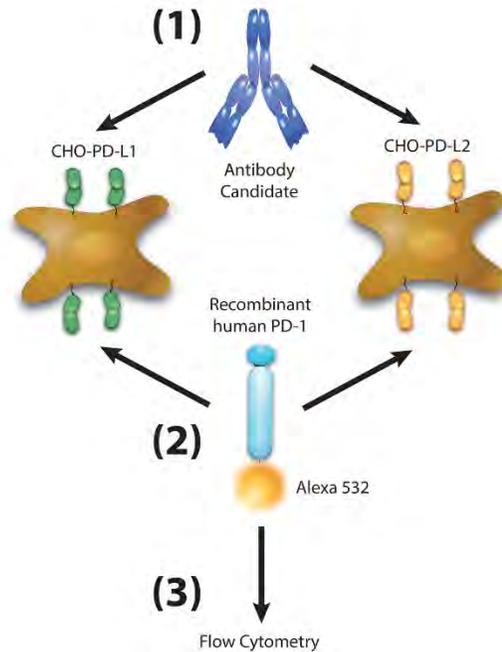


Dr. Filip Janku, PI of the trial, stated "the combination showed improved efficacy in difficult to treat indications more so than I would expect of either monotherapy."

2-46

4/3/20

Can PD-L1 and PD-L2 be Concurrently Targeted Based on Homology



PD-L1 vs PD-L2 = 35-40% identity

```

mPD-L2 MLLLLPYNLQLQHPVAAALFTYCAPREVTVDVGSSTVLECPDORRECTEISGLI...
hPD-L2 MIFLLLNLSLQLQHPVAAALFTYVVPREVTVDVGSSTVLECPDORRECTEISGLI...
mPD-L1 MRFIPAGIIFPTACCHLRAAFTVAPRDLYVVEYGSNVFRCRPFVREDDDLALVYVNE
hPD-L1 MRFIPVPIIFPTYWHLLRAAFTVAPRDLYVVEYGSNVFRCRPFVREDDDLALVYVNE
1 10 20 30 40 50

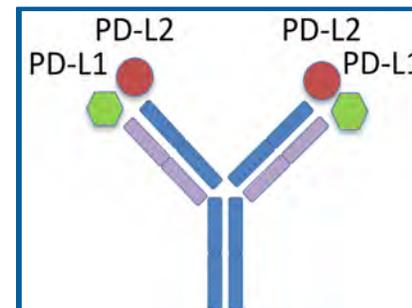
mPD-L2 ...RPSLQKV...EVDPSLQ...SRATLDEBQLFLKALFPHPSVQVDEGQVYCLVIC
hPD-L2 ...TNSLQKV...EVDPSLQ...KERAATLDEBQLFLKALFPHPSVQVDEGQVYCLVIC
mPD-L1 KSDGVLSVWAGSDKQSGVNFQASPSDDQLKSNALQCHDQVRLQDQVYCSLISH
hPD-L1 MEDRNITQVYVGSQKQVQSGVNFQASPSDDQLKSNALQCHDQVRLQDQVYCSLISH
61 70 80 90 100 110

mPD-L2 GAANDYRVLVYKVAQPSHSDRIISV...GCGQSVQVLTQCARQYFLARVWQ...VSV
hPD-L2 GAANDYRVLVYKVAQPSHSDRIISV...GCGQSVQVLTQCARQYFLARVWQ...VSV
mPD-L1 GGA...DYRRI...SVNA...PRKINORL...VDFV...SHELTCOARGYPRARV...WSSGDRVLEGG
hPD-L1 GGA...DYRRI...SVNA...PRKINORL...VDFV...SHELTCOARGYPRARV...WSSGDRVLEGG
121 130 140 150 160 170

mPD-L2 PANTSHRRAPDEGLYVTSVLRILKPPDRNFSCNENNAKMKRLTSA...ITDFSGRDEKVP
hPD-L2 PANTSHRRAPDEGLYVTSVLRILKPPDRNFSCNENNAKMKRLTSA...ITDFSGRDEKRTN
mPD-L1 KRSTVTRSRKCGHLDNVTSSRVNACRQVYCFENRSQGGONHAEELTIFELPAPHPFON
hPD-L1 KPTFTNKRREKLPNVTSSRVNACRQVYCFENRSQGGONHAEELTIFELPAPHPFON
181 190 200 210 220 230

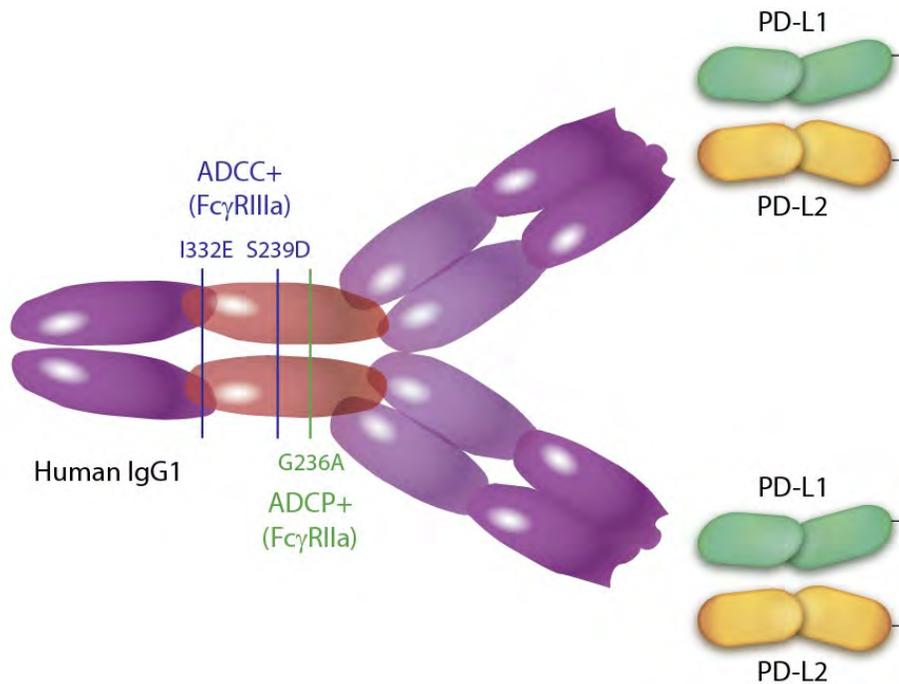
mPD-L2 RWFPEHVFHPACTIALFLAIVYVQRKRI
hPD-L2 RWFPEHVFHPACTIALFLAIVYVQRKRI
mPD-L1 RFI...RWFPEHVFHPACTIALFLAIVYVQRKRI
hPD-L1 RFI...RWFPEHVFHPACTIALFLAIVYVQRKRI
241 250 260 270 280 290
    
```

Could be affinity matured for both ligands.

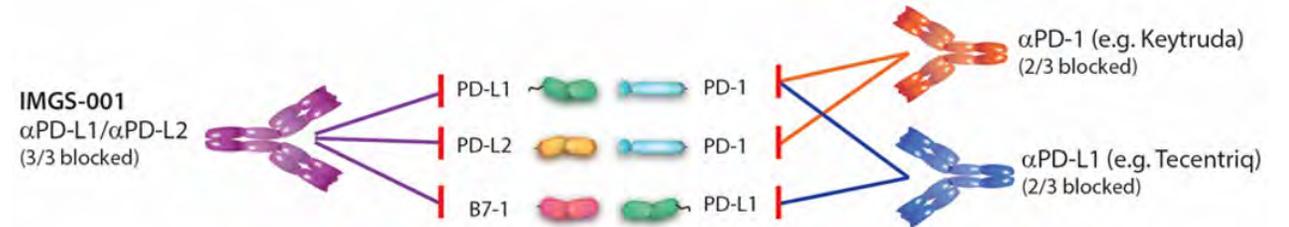


IMGS-001: Next Generation of Checkpoint Blockade

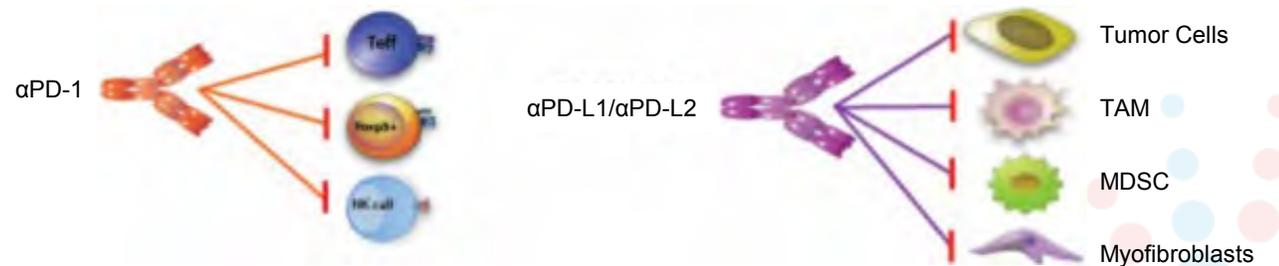
IMGS-001 is a cytotoxic, dual specific PD-L1/PD-L2 antibody with superior activity against both “hot” and “cold” tumors



IMGS-001 blocks all 3 PD-1 pathway inhibitory interactions



Unlike PD-1 inhibitors, IMGS-001 binds to suppressive stromal cells & tumors allowing it to gain potency through cytotoxic effector function

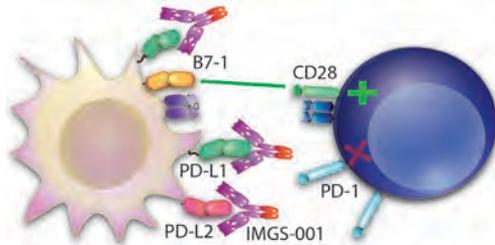


- Key Differentiators: Triple Blockade of PD-1 Pathway and Depletion of Tumors and Stroma

IMGS-001: A Multimodal Enhancer of Anti-Tumor Immunity

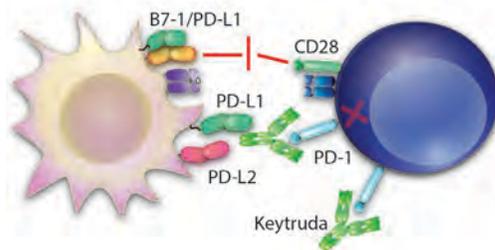
1) Complete PD-1 circuit blockade

IMGS-001

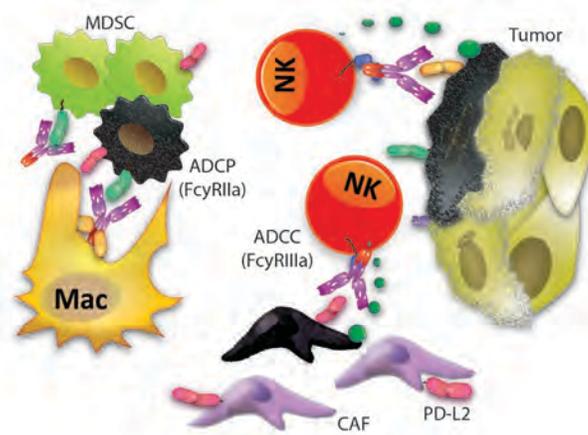


Blockade of PD-L1 and PD-L2 inhibitory cells through PD-1, and freeing of B7-1 to co-stimulate T cells through CD28.

Keytruda



2) Depletion of tumors and stroma



ADCC and ADCP mediated depletion of PD-L+ tumor and stroma opens TME to T cell infiltration and persistence. Also confers anti-metastatic potential against PD-L+ tumor cells.

Existing drugs cannot address the immunosuppressively dominant tumor stroma, and thus lack efficacy in the 55% of patients with immune “cold” cancers.

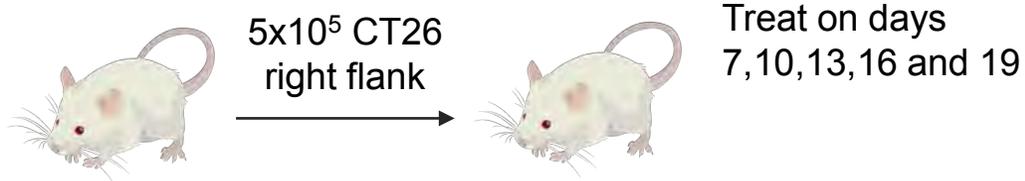
3) ADCP drives priming of T cell immunity



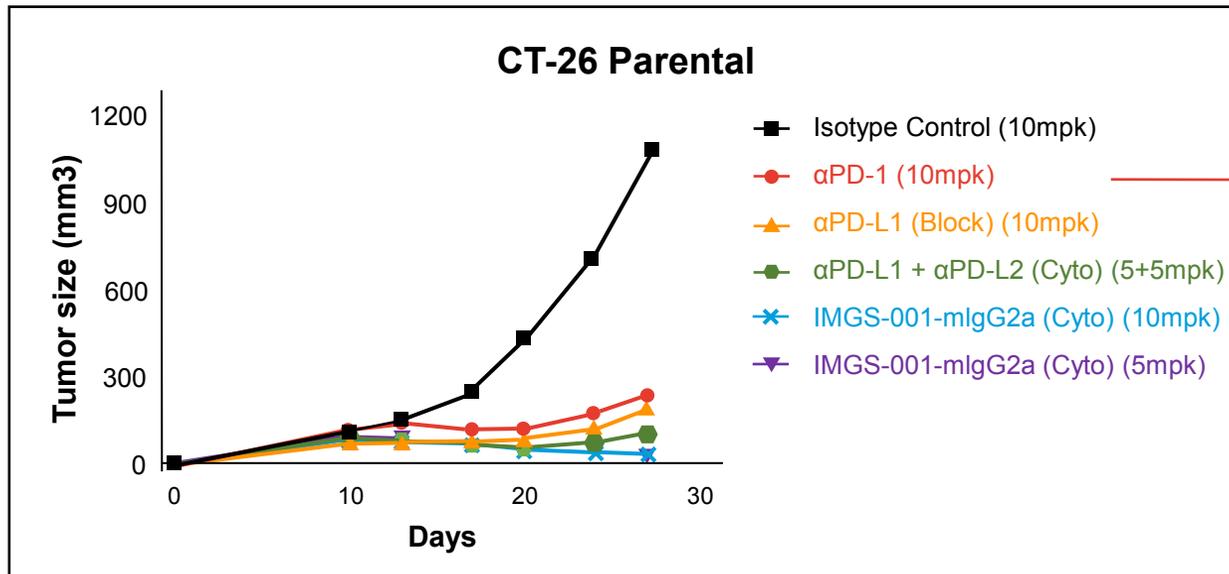
Phagocytosis of tumors leads to activation of the myeloid cell via FcyRIIa signalling. These myeloid cells then cross-present tumor antigen to T cells in the tumor and tumor draining lymph node which initiates, amplifies and supports adaptive immunity.

PD(L)-1 blocking antibodies fail in “immune ignorant” conditions where sub-optimal priming generates very low pre-existing tumor-specific T cell frequencies.

IMGS-001 Fully Regresses Hot CT26 Colon Cancer



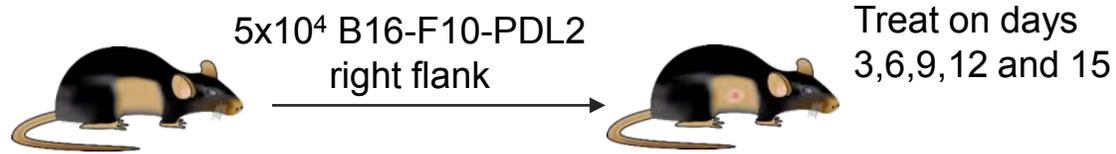
Note: CT-26 is a sub-optimal tumor model for the PD-L1/PD-L2 bispecific as PD-L2 is not expressed by the tumor cell.



A "hot" tumor = significant benefit from αPD-1

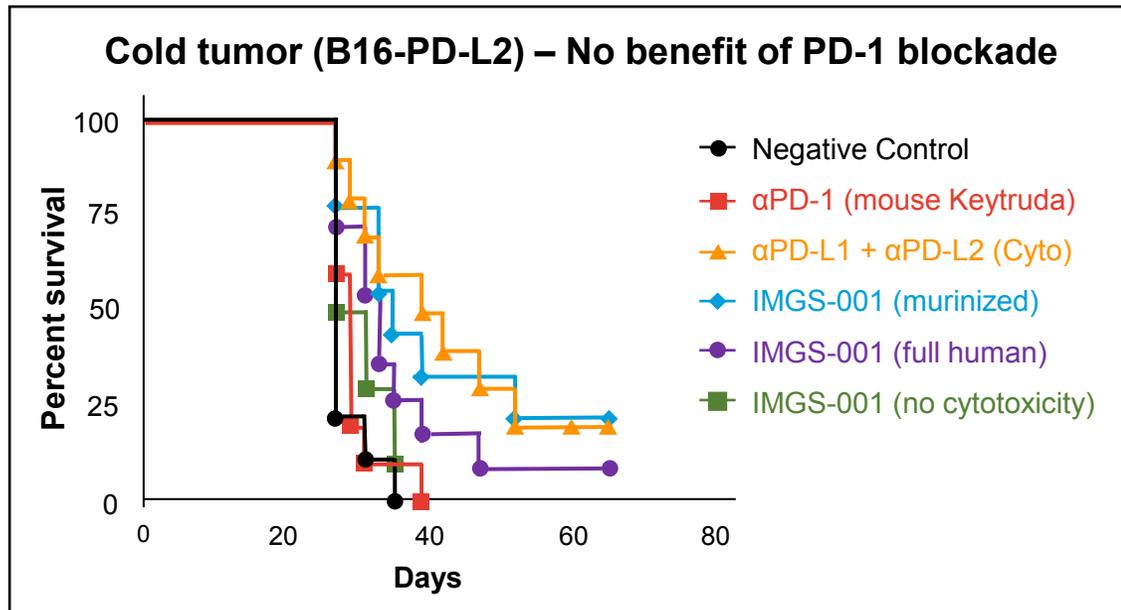
Cytotoxic PD-L1/PD-L2 (BiPDL) regresses all tumors even at half the αPD-1 dose

IMGS-001: PD-L1/PD-L2 Bispecific Prolongs Survival in Cold Melanoma



The majority of cancer patients fail to benefit from current anti-PD-1 antibodies.

ImmunoGenesis' mAb has the potential to treat all current PD-1 patients and address the unmet need in "cold" tumors.



A "cold" tumor = no benefit from αPD-1.

Cytotoxic PD-L1/PD-L2 (BiPDL) MAb lead doubles average survival and cures 20% of animals.

Cytotoxic effector function is required for therapy of "cold" cancers.



Company Overview

James A. Barlow, President & CEO

ImmunoGenesis: Advancing Immuno-Oncology with Next Generation Science



Founder among the pioneers of modern Immuno-Oncology



Clinical-stage Oncology pipeline with novel Immunotherapy treatments targeting “cold” tumors

ImmunoGenesis Team

FOUNDER



Michael A. Curran, PhD – Founder and SAB Head



**Dr. Curran collaborated closely with Nobel Laureate, Dr. James Allison, and is listed on the CTLA-4 patent along with Dr. Allison. Dr. Curran proposed, described and drove early development of the CTLA-4/PD-1 blockade combination which is still the most efficacious IO combo.*

MANAGEMENT



James A. Barlow, Jr. – CEO and President



William Tanner, PhD – Chief Financial Officer



Donald D.K. Strickland, MD – Consultant Chief Medical Officer



Federica Pericle, PhD – Consultant Chief Scientific Officer



BOARD



Robert Stein, PhD – BOD Member



Clifford Stocks – BOD Member



Andrew Strong, Esq. – BOD Member



Ted Koutouzis, MD – BOD Member



ADVISORS



David Hong, MD – Clinical Advisor

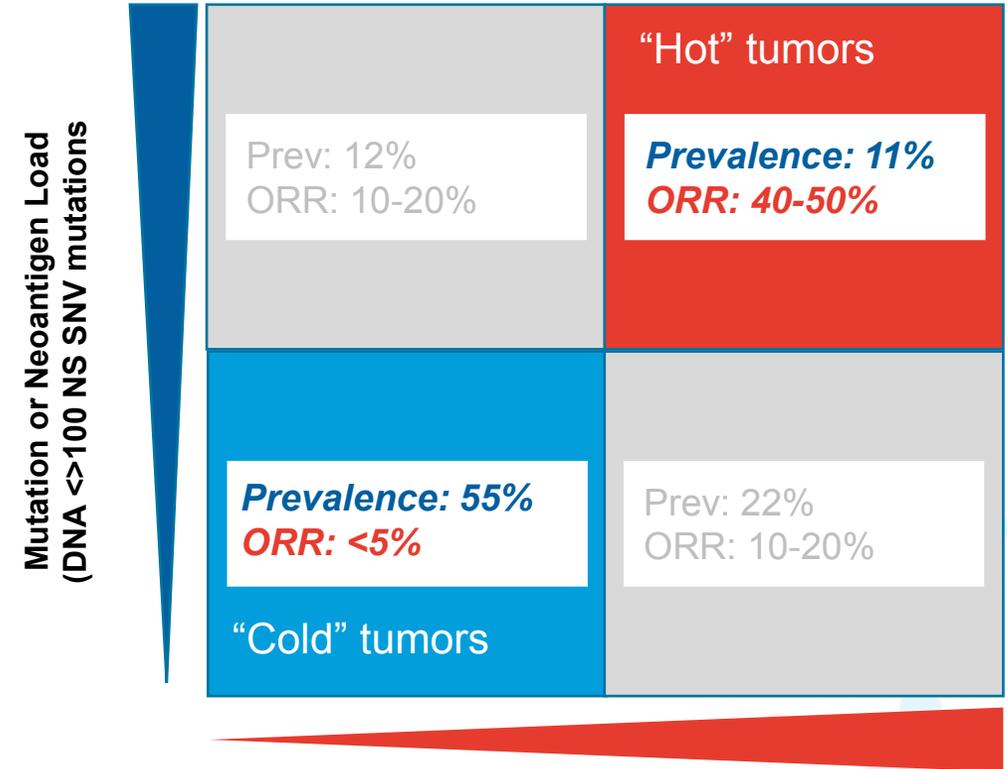


Darryl H. Patrick, VMD – Advisor on Pre-IND activities



“Cold” Tumors Represent a Significant Unmet Need

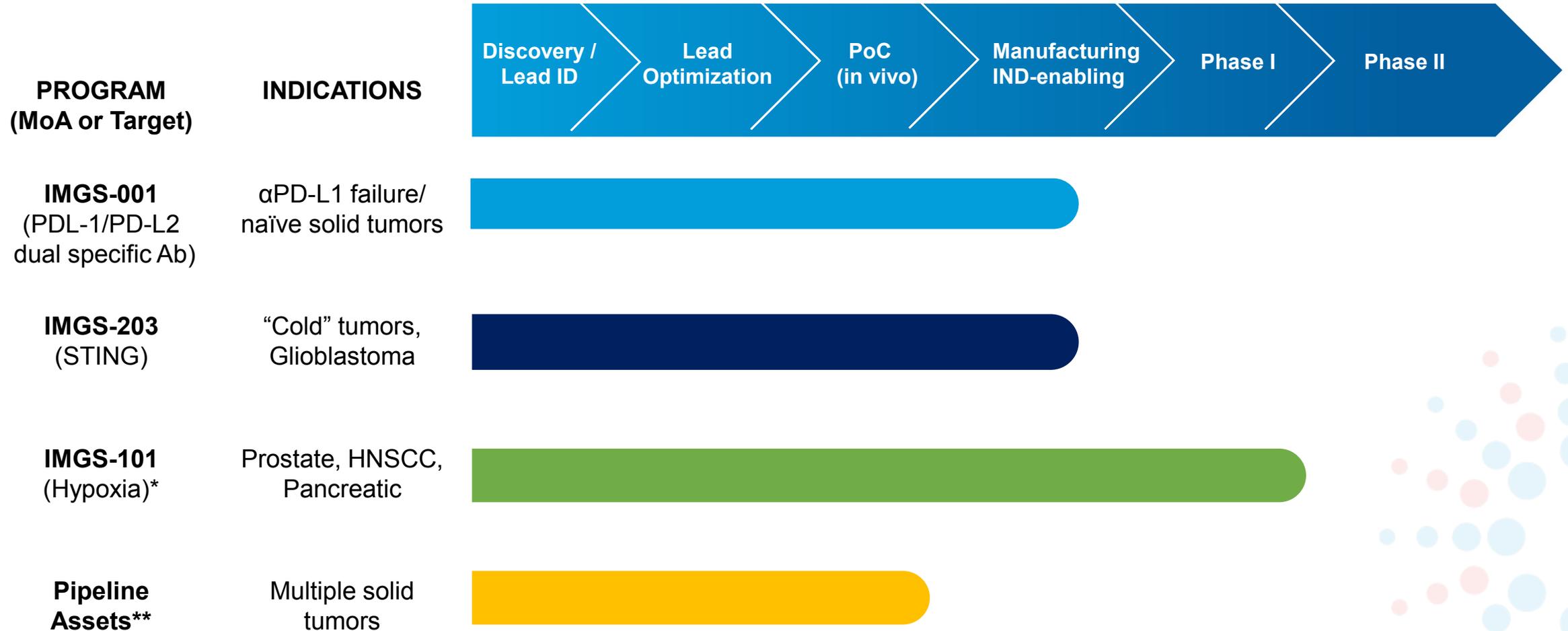
- Existing PD-(L)1 inhibitors: efficacy limited to hot tumors
- Drivers of cold tumor resistance:
 - Lack of activated T cells in tumor microenvironment (TME)
 - Immunosuppressive cells dominating TME
 - Impaired T cell trafficking to the tumor
- Need agents activating tumor-specific T cells and eliminating immunosuppressive cells from TME



Adapted from: Seiwert, T., and Kaufman D.R. JCO.2018.36.5_suppl.25
Journal of Clinical Oncology 36, 2018.

Prevalence of cold tumors: 5x greater than that for hot tumors

Oncology-Focused Pipeline Targeting “Cold” Tumors



* Investigator-initiated Study

** Includes a 4-1BB Agonist which can be combined with IMGS-001 in a bispecific as well additional PD-L targeting Abs which can be conjugated with the STING Agonist

IMGS-001: CPRIT Funding Will Enable Company to Begin Phase 1A/1B in Next 12 Months

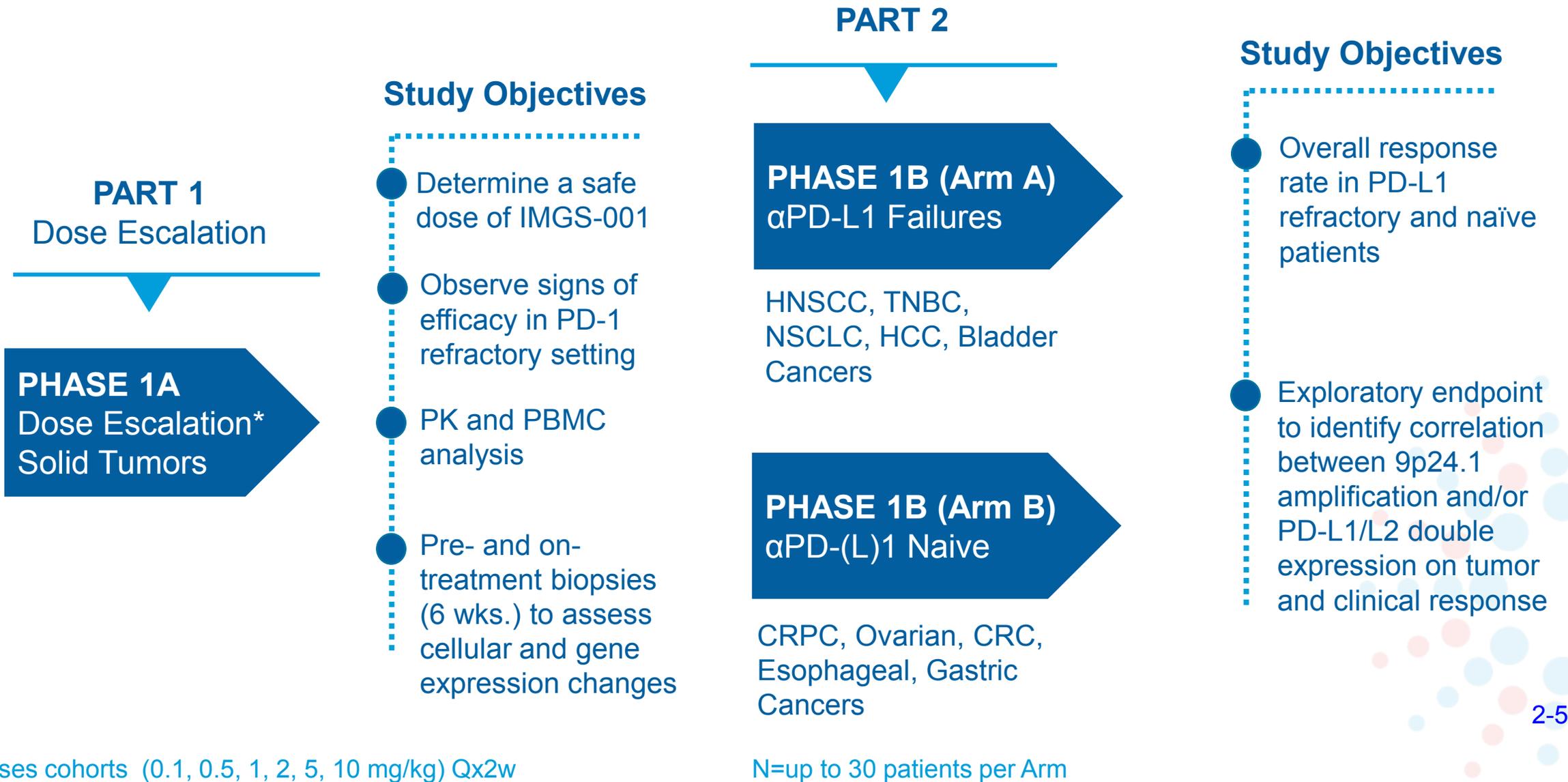
Master Cell Banking completed with excellent manufacturability profile
- Moved Manufacturing to FUJIFILM in Texas in connection with CPRIT Grant

FDA: proposed GLP-tox plan supports clinical development
- Will begin Non-GLP Cyno Tox in May and GLP Cyno Tox in July/August
- Pre-IND Meeting with FDA in Q3 2021

Phase 1A/1B clinical trial design finalized (Dr. David Hong, MD Anderson)
- Plan to hold Clinical Ad Board in April

Conducting additional IND-enabling work in 2021
- Humanized mouse efficacy, biomarker validation, and dose/schedule testing

IMGS-001: Phase 1A/1B Clinical Trial Plan



IMGS-001 – Tri-targeting Bispecific Development Programs



IMGS-001 + 4-1BB

Triple blockade of PD-1 pathway inhibitory interactions and 4-1BB Agonism

Pair best PD-1 pathway blocking compound with important agonist

If safe and effective, immediately move to best-in-class among numerous PD-1/4-1BB combinations in development

IMGS-001 + CTLA-4*

Improve on a combination that has already demonstrated effectiveness

Pair best PD-1 pathway blocking compound with CTLA-4 inhibitor in single molecule

CTLA-4 would have built-in effector function to further enhance efficacy

*Dependent on licensing a CTLA-4 with effector function.

CPRIT Funding Will Drive Establishment of Proof of Concept for IMGS-001

Goals for Phase 1A/1B Trial:

- Generate initial proof that IMGS-001 is a superior foundation of PD-1 pathway blockade that is effective in cold tumors
- Demonstrate opportunity for future trials to layer combination treatments on top of IMGS-001 to drive efficacy higher
- Show potential for molecular indication across different cancers for tumors with a 9p24.1 amplification
- Allow for platform expansion into tri-targeting bispecifics



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT: AGENDA ITEM 6: CHIEF EXECUTIVE OFFICER REPORT
DATE: FEBRUARY 10, 2021

I will address the items detailed below in my Chief Executive Officer Report presented at the February 17 Oversight Committee meeting. I have included copies of the November - December 2020 and January 2021 CPRIT Activity Updates behind this memo and attachments for your reference.

Oversight Committee Appointment

On February 1 Governor Abbott reappointed current Presiding Officer Dee Margo to the Oversight Committee for a new term to expire January 31, 2027. Mr. Margo's previous term expired January 31, 2021.

FY 2021 Grant Awards Funds Available and CPRIT Dashboard (Attachments 1 and 2)

CPRIT has \$248.4 million available from fiscal year 2021 appropriations for grant awards. There are sufficient funds to cover the Program Integration Committee's recommendations that Dr. Willson will present at the February 17 meeting. I have also included CPRIT's dashboard of metrics the agency tracks on a regular basis.

CPRIT's Response to COVID-19 Related Issues

CPRIT staff continue to work remotely. Unless directed differently by state leadership, CPRIT will maintain this policy and reassess our status at the end of May.

The Chief Operating Officer reports that grantees are submitting fewer COVID-related expense claims as operations adjust for the new normal.

Personnel

CPRIT currently has 34 of our 36 full-time equivalent (FTE) positions filled.

On March 1, Tracey Davies will join CPRIT in a new senior staff position, Chief Intellectual Property and Strategic Initiatives Officer. As CPRIT enters its second decade, the agency's portfolio of intellectual property created and advanced with CPRIT funding continues to grow. Ms. Davies will help guide the strategic development of our IP portfolio as well identify new ways to integrate our cancer prevention and research efforts with new public/private partnerships

that promote Texas’ research and applied science superiority. She is a licensed patent attorney with more than 20 years of experience in intellectual property and broad-based legal expertise advising life science companies at all stages of development. Prior to joining CPRIT, she was a partner at a major multinational law firm specializing in patent litigation.

I will introduce Ms. Davies to the Oversight Committee on February 17.

Legislative Session Update

Senate and House Committee Assignments and Budget Hearing Status

Lieutenant Governor Patrick announced his standing committee assignments for the 87th Texas Legislature. Senator Jane Nelson again chairs the Senate Committee on Finance and Senator Lois Kolkhorst chairs the Senate Committee on Health and Human Services.

Speaker Phelan announced his appointments February 4. Notable assignments include Rep. Greg Bonnen to chair the House Committee on Appropriations and Rep. Stephanie Klick to chair the House Committee on Public Health.

We presented our budget request to the Senate Committee on Finance on February 9. As of this writing the House Committee on Appropriations has not met to organize. I expect them to appoint subcommittees soon and begin agency budget hearings the week of February 15. I will update you on their schedule on February 17.

General Appropriations Bills

The House and Senate (Senate Bill 1 by Nelson) released the bills January 21. Both provide CPRIT’s full, constitutionally authorized annual appropriation of \$300 million less the required transfer of \$3.1 million per year to the Cancer Registry at the Texas Department of State Health Services. Governor Abbott released his budget priorities for fiscal years 2022-2023 on February 5. The Governor’s priorities do not address CPRIT.

The table below compares the House and Senate versions related to CPRIT’s budget requests.

Item	House	Senate
Base Adjustment for Ongoing Operating Costs	No	Yes
8 Full-Time Equivalent Positions	No	Yes
Transfer Authority	Yes, partial	Yes
Chief Scientific Officer Exempt Salary Increase	No	No
SWCAP Base Adjustment (new in January)	No	No

It is notable that the Senate bill provides all CPRIT’s requested items except the 10% Chief Scientific Officer exempt salary increase and the Statewide Cost Allocation Plan (SWCAP) adjustment discussed below. It is rare for an introduced appropriations bill to include most of an agency’s significant requests. This is a definite sign of confidence in CPRIT.

CPRIT added to our request another exceptional item to transfer \$450,000 per year from the research and prevention programs to indirect administration. This is necessary because the Comptroller Office's notified CPRIT in early January of a 552% increase in CPRIT's fiscal year 2020 SWCAP amount. The fiscal year 2020 SWCAP is based on state expenditures and state agencies' use of central state services in fiscal year 2018. CPRIT began using the state's Centralized Accounting and Payroll/Personnel System (CAPPS) Financial module for our accounting and procurement processes in fiscal year 2018. CPRIT will continue to use the CAPPS module so we must plan for CPRIT's new, higher SWCAP allocation remaining at this increased level going forward.

We do not expect to have sufficient unused budget in fiscal year 2021 to accommodate the increased SWCAP this year. Therefore we will need to request from the Legislative Budget Board (LBB) a transfer in fiscal year 2021 from our research and prevention line items of appropriations to indirect administration.

- *Base Adjustment for Ongoing Operating Costs*

The Senate bill incorporates CPRIT's requested adjustments except the SWCAP charge described above for ongoing operating costs. The House bill provides a "base" (carryforward of previous appropriations amounts with minimal adjustments mandated in the budget instructions) that the House Committee on Appropriations will use to mark up in subcommittees. This is a more traditional approach to an agency's budget request than the Senate's bill. Unlike many state agencies, state leadership did not instruct CPRIT to make any reductions from its base request for 2022 and 2023.

- *Budget Transfer Authority*

Currently, the Legislative Budget Board (specifically the Chairs of House Appropriations and Senate Finance, the Lieutenant Governor, and the Speaker) must each individually approve a CPRIT transfer request before the agency may transfer appropriated funds between budget line items. These transfer requests are non-controversial but necessary to maintain operational stability. However, because of the multiple signoffs required for approval, CPRIT's budget transfer requests have languished administratively for months, with our most recent request taking more than 115 days to get approved.

The Senate's budget proposal, which tracks our request, authorizes CPRIT's CEO, with Oversight Committee acknowledgement, to transfer up to 20 percent from one line item to another. Although CPRIT must report the transfer to the LBB, the Senate version does not require additional approval before the transfer may occur. This is the standard budget transfer provision for most state agencies.

The House's version takes a different approach. It proposes limiting the window for rejecting CPRIT's budget transfer request to 30 days. Unless the House Appropriations Chair, Senate Finance Chair, the Lieutenant Governor or the Speaker specifically reject CPRIT's request, CPRIT may make the budget transfer on the 31st day. The House's

proposed change is a significant improvement over CPRIT's current provision, but still treats CPRIT differently from most state agencies

- *Chief Scientific Officer Exempt Salary Increase*

The legislature typically addresses exempt salaries in the last days of the budget conference committee in May. We will continue to work with the Senate and the House to explain the rationale for the salary increase.

Notable Legislation

- Senate Bill 71 - Senator Borris Miles filed legislation amending CPRIT's statute (Tex. Health & Safety Code §102.255(d)) to allow research institutions or their affiliated centers to use the federal indirect rate as a credit to offset CPRIT's matching requirement. The credit is already available to institutions of higher education as defined by the Texas Education Code, but the amendment addresses the research institutions that do not qualify under Education Code designation.
- Senate Joint Resolution 17 and Senate Bill 264 - Senator Jose Menéndez filed legislation to create the Texas Research Consortium to Cure Infectious Diseases (TRANSCEND) with a \$3 billion constitutional bond authorization. Senator Menéndez has explained that he intends CPRIT to serve as a model for the new agency.

Chief Scientific Officer Search (Attachment 3)

CPRIT's Chief Scientific Officer Dr. Jim Willson plans to leave CPRIT this summer. The Oversight Committee will consider an executive search firm contract at the February 17 meeting. I have attached a memo describing the CSO search process and interview team. We hope to have a new CSO in place by the end of August.

CEO Report Pursuant to Texas Health & Safety Code § 102.260(c) (Attachment 4)

State law requires CPRIT's CEO to report to the Oversight Committee at least annually on the progress and continued merit of each research program funded by CPRIT. I have included my account of the continued progress and merit of each of CPRIT's programs as attachment 4.

Cancer Prevention and Research Institute of Texas Fiscal Year 2020 Annual Report

CPRIT released our fiscal year [2020 annual report](#) on January 31 through our website. This is the first time that we present the annual report exclusively in an online format. This platform provides CPRIT's stakeholders a more interactive experience to review the many accomplishments and advances made by CPRIT's grantees in fiscal year 2020. For example, the 2020 report incorporates seven video clips of grantees talking about their research and prevention projects and two interactive maps that show all active prevention projects by county and legislative district, as well as the expansion of successful breast and colorectal cancer screening projects over ten years.

The new format provides greater insight into CPRIT’s statutory mission, our priorities, and the economic and social burden that cancer costs the state by featuring grant projects. We feature more than 60 examples of grantee progress at 41 institutions, organizations, and companies. In recognition of the unprecedented challenges posed by the COVID-19 pandemic, this report also includes examples of the cancer community’s response and the devastating impact on cancer prevention efforts that will affect Texans for years to come.

Deputy Executive Officer and General Counsel Kristen Doyle will provide a brief presentation of the report.

CPRIT has awarded **1,584** grants totaling **\$2.661 billion**

- 244 prevention awards totaling \$277.7 million
- 1,340 academic research and product development research awards totaling \$2.383 billion

Of the \$2.383 billion in academic research and product development research awards,

- 30.6% of the funding (\$730.0 million) supports clinical research projects
- 24.6% of the funding (\$586.0 million) supports translational research projects
- 28.5% of funding (\$679.6 million) supports recruitment awards
- 13.8% of the funding (\$327.7 million) supports discovery stage research projects
- 2.5% of funding (\$60.0 million) supports training programs.

CPRIT has 3 open Requests for Applications (RFAs)

- 3 Research Recruitment

FY 2021 GRANT AWARD FUNDS AVAILABLE

General Obligation Bond Proceeds

	Prevention	Academic / Product Development Research	1% Grant Funding Buffer	Operating Budget	Total Appropriations
Available Appropriated Funds	\$ 28,035,081	\$ 254,738,136		\$ 17,226,783	\$ 300,000,000
Approved Adjustment to Operating Budget		\$ (2,484,576)		\$ 2,484,576	
Appropriations Transfer to DSHS		\$ (3,118,032)		\$ 3,118,032	
Adjusted Appropriations	\$ 28,035,081	\$ 249,135,528		\$ 22,829,391	\$ 300,000,000
Total Available for All Grants			\$ 277,170,609		
1% of Total Available Grant Funding			\$ 2,771,706		
Adjusted Grant Award Funding	28,035,081	\$ 246,363,822			\$ 274,398,903
	Prevention Grants	Academic Research Grants	PD Research Grants		
Total Available for Grant Awards (Total GO Bond Proceeds Less Operating Budget)	\$ 28,035,081	\$ 174,394,870	\$ 74,740,658		\$ 277,170,609
Total Available for Grant Awards Incorporating 1% Grant Funding Buffer	\$ 28,035,081	\$ 172,454,675	\$ 73,909,147		\$ 274,398,903

Announced Grant Awards

11/18/20 Recruitment Awards	\$ -	\$ 26,000,000	\$ -		
	\$ -	\$ -			
	\$ -	\$ -	\$ -		
	\$ -	\$ -			
Announced Grant Award Subtotal	\$ -	\$ 26,000,000	\$ -	\$ -	\$ 26,000,000
Grant Award Adjustments					
	\$ -	\$ -	\$ -		\$ -
	\$ -	\$ -	\$ -		\$ -
	\$ -	\$ -	\$ -		\$ -
	\$ -	\$ -	\$ -		\$ -
Revised Grant Award Subtotal	\$ -	\$ 26,000,000	\$ -		\$ 26,000,000
Uncommitted Funds as of November 30, 2020	\$ 28,035,081	\$ 146,454,675	\$ 73,909,147		\$ 248,398,903

Pending Grant Awards-PIC Recommendations

Recruitment Awards (2)		\$ 12,000,000			
Pending Grant Award Subtotal	\$ -	\$ 12,000,000	\$ -		\$ 12,000,000
Total Pending Grant & Grant Funds Committed	\$ -	\$ 38,000,000	\$ -		\$ 38,000,000
Uncommitted Funds as of February 2, 2021	\$ 28,035,081	\$ 134,454,675	\$ 73,909,147		\$ 236,398,903
1% Grant Funding Buffer	\$ -	\$ 1,940,195	\$ 831,511		\$ 2,771,706
Total Remaining Funds	\$ 28,035,081	\$ 136,394,870	\$ 74,740,658		\$ 239,170,609

Operating Budget Detail

Indirect Administration	\$ 4,380,053
Grant Review & Award Operations	\$ 15,331,306
Subtotal, CPRIT Operating Costs	\$ 19,711,359
Cancer Registry Operating Cost Transfer	\$ 3,118,032
Total, Operating Costs	22,829,391

**CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2021**

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
ACCOUNTABILITY														
Announced Grant Awards			62										62	
New Grant Contracts Signed	13	33	6	5	10								67	
New Grant Contracts In Negotiation			12										12	
Grant Reimbursements Processed (#)	208	195	209	142	128								882	
Grant Reimbursements Processed (\$)	\$ 24,277,590	\$ 21,609,925	\$ 11,437,454	\$ 25,234,475	\$ 14,976,404								\$ 97,535,848	
Revenue Sharing Payments Received	\$ -	\$ -	\$ 44,809	\$ -	\$ -								\$ 44,809	\$ 4,709,308
Grants Awarded (#)/ Applications Rec'd (#)	18%	18%	19%	18%	18%									
Grantee Compliance Trainings	0	4	2	1	0								7	
Grantee Compliance Monitoring Visits	0	0	2	2	3								7	
Awards with Delinquent Reimbursement Submission (FSR)			14											
Awards with Delinquent Matching Funds Verification			0											
Awards with Delinquent Progress Report Submission			4											
MISSION														
Open RFAs	11	13	13	13	16									
Prevention Applications Received	0	12	0	0	0								12	881
Product Development Applications Received	0	0	0	0	36								36	597
Academic Research Applications Received	0	17	2	4	162								185	7,730
Help Desk Calls/Emails	85	123	72	94	225								599	
Number of Research Grants Announced (Annual)	0		52										52	
Recruited Scientists Contracted														228
Number of Product Development Grants Announced (Annual)			2										2	
Life Science Companies Recruited (in TX)														11
Number of Product Development Jobs Created & Maintained														738
Number of Prevention Grants Announced (Annual)			8										8	
Total Number of Education, Navigation and Training Services			177,077										177,077	
Total Number of Clinical Services			57,327										57,327	
Published Articles on CPRIT-Funded Projects (#)														
Clinical Studies (#)														160
Number of Patent Applications														
Number of Patents Resulting from Research														
TRANSPARENCY														
Total Website Hits (Sessions)	8,582	8,651	10,366	6,975	9,422									
Total Unique Visitors to Website (Users)	6,409	6,646	8,474	5,351	6,762									



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT: 2021 CHIEF SCIENTIFIC OFFICER RECRUITMENT PROCESS
DATE: FEBRUARY 10, 2021

Summary

CPRIT's Chief Scientific Officer (CSO) Jim Willson plans to leave CPRIT within the next eight months. CPRIT will use an executive search firm approved by the Oversight Committee to identify candidates to fill the CSO position. In consultation with Presiding Officer Margo and consistent with the CEO's statutory responsibility to hire the CSO, I have appointed an interview committee to recommend candidates from which I may select the finalist. The interview committee's work will begin in March and may continue through June.

Discussion

The CEO is statutorily responsible for hiring the CSO. CPRIT has used the same process in 2008, 2012, and 2015 to hire each of CPRIT's three CSOs. This process begins with an executive search firm that conducts a national search for preeminent candidates, facilitates the interview process, and serves as a resource to the interview committee. I have assembled an interview committee to review applications, interview applicants and recommend candidates for my consideration.

Executive Search Firm to Bring Forward Qualified Candidates

Consistent with the state procurement process, CPRIT received approval from the Comptroller of Public Accounts on January 4 to release a request for proposals (RFP) for an executive search firm to conduct a national search for exceptional CSO candidates and facilitate the selection process. Three applicants submitted proposals by the January 26 deadline. A CPRIT team evaluated the proposals and CPRIT is negotiating with our preferred candidate. Because the proposed contract will exceed \$100,000, the Oversight Committee must approve the contract. Contract consideration is an agenda item for the February 17 Oversight Committee meeting.

Convening an Interview Committee to Recommend CSO Finalists

It has been CPRIT's practice to include Oversight Committee members on the interview panel used to select candidates for chief program officer positions. Not only do I benefit from the Oversight Committee's significant expertise, but these are signature appointments that Oversight

Committee members must have confidence in to act on award and policy recommendations. I have also included representatives from the Scientific Review Council, academic research advisory committees and CPRIT staff members. I will act as an *ex officio* member and sit in on all interviews and discussions of the interview committee.

The 2021 interview committee consists of the following members:

- Chair, Bill Rice, M.D., Oversight Committee member
- Mahendra Patel, M.D., Oversight Committee Assistant Presiding Officer
- Cindy Barberio Payne, Oversight Committee member
- Will Montgomery, Oversight Committee member
- Richard Kolodner, Ph.D., Chair, Scientific Review Council; Member, Ludwig Institute for Cancer Research, San Diego Branch; Distinguished Professor of Medicine and of Cellular and Molecular Medicine, UCSD School of Medicine
- Kent Osborne, M.D., Director Emeritus, Dan L. Duncan Comprehensive Cancer Center, Baylor College of Medicine
- Navkiran Shokar, M.A., M.D., M.P.H., Interim Associate Dean for Clinical Research; Vice Chair for Research, Department of Family & Community Medicine; Director, Cancer Prevention & Control, Center of Emphasis for Cancer; Texas Tech University Health Sciences Center El Paso
- Jim Willson, M.D., CPRIT Chief Scientific Officer
- Ramona Magid, CPRIT Chief Prevention Officer
- Patty Moore, Ph.D., CPRIT Senior Program Manager for Academic Research
- Lisa Nelson, CPRIT Operations Manager

Interview Committee Logistics

The interview committee's work reviewing applications and culling applicants will begin in March, with interviews taking place in April and May. My plan is that we will have identified a finalist or finalists by mid- to late June.

We will meet with the search firm staff to discuss logistics and refine the schedule. Based upon our experience, I expect that the committee will interview eight to ten applicants. We will conduct initial videoconference interviews lasting 60 – 90 minutes. Follow-up interviews and additional processes will be determined in the weeks ahead.

I will provide updates on the recruitment to the full Oversight Committee as developments warrant.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT: FY 2020 REPORT ON PROGRAM MERIT AND PROGRESS PURSUANT TO TEXAS HEALTH & SAFETY CODE § 102.260(C)
DATE: FEBRUARY 17, 2021

Summary

Texas Health and Safety Code § 102.260(c) requires the Chief Executive Officer to report at least annually to the Oversight Committee on the progress and continued merit of each research program. I am pleased to report that despite the interruptions caused by COVID-19 this marked another year of progress for CPRIT and its Academic Research, Prevention, and Product Development Research programs. In fiscal year 2020 CPRIT awarded 134 grants totaling \$254 million to 31 academic institutions, community organizations, and companies throughout the state. Key metrics indicate that CPRIT is affecting Texas' national standing in both cancer research and the biomedical industry. CPRIT's investment in intellectual and research support infrastructure in Texas is attracting, creating, and expanding the research capabilities of our institutions of higher education and the state's life science industry, expediting innovation, and increasing the likelihood of breakthroughs in cancer prevention and cures.

My report provides an overview illustrating the progress made in advancing CPRIT's mission to create and expedite innovation in cancer research and cancer prevention. Aligning program activities with the program priorities adopted by the Oversight Committee is a good gauge of progress and merit; this report highlights each program's implementation of the fiscal year 2020 program priorities. CPRIT's 2020 [Annual Report](#) provides more information on CPRIT program priorities and awards, including a summary of research findings reported by grantees in fiscal year 2020 and notable grantee highlights.

Regarding progress made by individual grant projects within each of CPRIT's three programs, Texas Administrative Code § 703.21 requires all CPRIT grantees to submit progress reports at least annually. Outside experts evaluate these progress reports to ensure that the grantee has made appropriate progress and should continue work under the grant. To the extent that an expert reviewer determines that a grant project is not making progress towards the project goals and objectives, CPRIT has several options, including contract termination.

Academic Research Program

CPRIT's Academic Research Program supports innovative and meritorious projects that are discovering new information about cancer that can lead to prevention, early detection, and cures; translating new and existing discoveries into practical advances in cancer diagnosis and treatment; and increasing the prominence and stature of Texas in the fight against cancer.

In fiscal year 2020, CPRIT's Oversight Committee approved 109 Academic Research and Recruitment Awards totaling \$175.1 million. Academic Research grantees achieved several "firsts" during fiscal year 2020 that highlight the continued growth and progress in cancer research. The program debuted a new grant mechanism, Early Clinical Investigator Awards, which CPRIT gave to four promising clinical investigators at Baylor College of Medicine, The University of Texas M.D. Anderson Cancer Center, and The University of Texas Southwestern Medical Center. Texas A&M Corpus Christi received a High-Impact/High-Risk Research Award, which is the institution's first CPRIT grant award. Texas Tech University School of Veterinary Medicine and Texas A&M Engineering Experiment Station each recruited their first CPRIT scholar. Texas Tech University Health Sciences Center Amarillo received its first Core Facility Support Award.

Academic Research Program Priorities

The Oversight Committee adopted the following fiscal year 2020 program priorities for the Academic Research Program:

- Recruitment of outstanding cancer researchers to Texas;
- Investment in core facilities;
- A broad range of innovative, investigator-initiated research projects;
- Implementation research to accelerate adoption and deployment of evidence-based prevention and screening interventions;
- Computational biology and analytic methods;
- Childhood cancers; and
- Hepatocellular cancer.

CPRIT Scholars continue to serve as a shining example of CPRIT's positive impact on cancer research in Texas. Through August 31, 2020, twenty-one institutions across the state have recruited 213 CPRIT scholars. Several CPRIT scholars focus on childhood cancer research, which CPRIT has prioritized since 2014. The University of Texas Southwestern Medical Center

recruited Dr. Joshua Mendell, M.D., Ph.D, from Johns Hopkins University in 2010. His research on genes and genetic regulatory pathways and his contributions to a team of researchers on microRNA pathways found that those pathways “play an especially important role in several cancers that occur in children.”

Several of CPRIT’s Core Facility Support Awards also have a direct impact on childhood cancer research. The Greehey CCRI Xenograft & Cell-Lines Core at The University of Texas Health Science Center at San Antonio develops animal models that researchers can use to test new therapies in children whose cancer has relapsed or who are from minority groups that typically have not responded well to current treatments. Dr. Mendell’s work and the Core Facility at UT-Health San Antonio are just two examples that show how CPRIT’s focus on childhood cancer as an Academic Research program priority has resulted in \$301 million in grants - approximately 11% of CPRIT’s portfolio - supporting childhood cancer projects. CPRIT’s commitment is proportionally three times more than the national level. CPRIT has created a landing page on our website to highlight the advances CPRIT grantees are making in the fight against childhood and adolescent cancers.

Prevention Program

CPRIT’s Prevention Program continues to support effective, evidence-based prevention programs that are available to underserved populations in the state. Prevention Program grants help Texans reduce the risk of cancer, identify cancers earlier, and assist people in finding cancer treatment. Through August 31, 2020, prevention grantees have provided 6.8 million prevention services, including 3 million clinical services with 379,553 people receiving their first cancer screening through a CPRIT-funded project. These efforts ease the burden of cancer in Texas.

The Oversight Committee approved 18 prevention grants during fiscal year 2020 totaling \$27.6 million. Some of the notable prevention outreach highlights include Texas Tech University Health Sciences Center El Paso’s Dr. Jennifer Salinas who delivered a presentation about obesity related cancer prevention in El Paso at the American Public Health Association 2019 annual conference. The U.S. Army followed up to learn more about the project.

In a commentary published in the July 30, 2020, issue of the *Journal of General Internal Medicine*, Dr. Michael Pignone highlighted the important role the U.S. Postal Services plays in improving health care. Dr. Pignone, Director of the Program on Cancer Prevention & Control, Livestrong Cancer Institutes, Dell Medical School at The University of Texas at Austin, reported that mailed FIT testing program funded by CPRIT would not be cost-effective without the infrastructure of the USPS.

Ellen Shohet, M.N., program manager with the “Passport for Care” project led by Baylor College of Medicine’s Dr. David Poplack, presented at the Children’s Oncology Group meeting in Atlanta in September 2019. Ms. Shohert explained that their program “is national and now international as we are available in almost 140 children’s oncology clinics; just wanted [CPRIT] to know how far and impactful your reach really is with this project!”

Prevention Program Priorities

The Oversight Committee adopted the following fiscal year 2020 Prevention Program priorities:

- Populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence;
- Geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence; and
- Underserved populations.

A CPRIT-funded collaboration between Baylor College of Medicine, Harris Health System (the county’s safety-net provider), and other academic and community partners is one example of prevention grantees serving underserved populations. The Community Network for Cancer Prevention (CNCP) project provides cancer screenings to underserved populations in Harris County, which is home to a large medically underserved population, with uninsured rates of 28% (compared to 10% nationally). The CNCP uses novel techniques to reach medically underserved populations through culturally targeted, entertainment-based cancer screening education that include theatre troupes who perform in African American, Hispanic, and Vietnamese communities.

This program received several CPRIT grants to provide education on cervical cancer, colorectal cancer, and breast cancer screenings, as well as HPV vaccination and tobacco prevention education. The continued success of the CNCP is evident. In 2010, prior to CNCP, only 24% of age-eligible patients at Harris Health received a FIT for colorectal cancer screening and 29% received a Pap test for cervical cancer screening; the current rates are many times higher (69% and 78% in 2019, respectively).

Product Development Research Program

CPRIT’s Product Development Research Program funds innovative and scientifically meritorious product development projects with the potential of translating research discoveries into commercial products that can benefit cancer patients. In fiscal 2020, the Oversight

Committee approved seven Product Development Research awards totaling \$51.6 million. CPRIT has awarded 49 Product Development Research grants to 42 companies totaling \$480 million since 2010.

The Product Development Research program benefits not only cancer patients, but like CPRIT's recruitment grants, the Product Development Research awards are a vital component in building the life sciences infrastructure and community in Texas. Through August 31, 2020, CPRIT companies raised \$3.4 billion in additional investments after their CPRIT awards (a 7:1 funding ratio). These additional investments and activities testify to the quality of the CPRIT-funded projects and CPRIT's review process. CPRIT-funded companies continue to help not only the life sciences ecosystem, but also the Texas economy at large with \$626 million in annual economic benefits for the state. Companies that CPRIT has invested in employ 700 Texans.

Product Development Research Program Priorities

The Oversight Committee adopted the following fiscal year 2020 Product Development Research Program Priorities:

- Funding novel projects that offer therapeutic or diagnostic benefits not currently available, i.e., disruptive technologies;
- Funding projects addressing large or challenging unmet medical needs;
- Investing in early-stage projects when private capital is least available;
- Stimulating commercialization of technologies developed at Texas institutions;
- Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life sciences expertise, especially experienced C-level staff to lead to seed clusters of life science expertise at various Texas locations; and
- Providing appropriate return on Texas taxpayer investment.

In fiscal year 2020, two companies that spun out companies to develop promising discoveries from M.D. Anderson Cancer Center received CPRIT product development awards. Asyria Therapeutics, a Seed Award grant recipient, develops a novel antibody drug for breast cancer, myelomas, and pancreatic cancer treatment while ImmunoGenesis, a Texas Company award recipient, develops a novel antibody drug active across immune "hot" and "cold" cancers. Two more companies received CPRIT company awards in fiscal year 2020 to develop research discoveries made at The University of Texas Southwestern Medical Center. Barricade Therapeutics is working on a first-in-class small molecule for the treatment of colorectal cancer and Texas Magnetic Imaging Technology is creating an integrated interior magnetic resonance imaging and medical linear accelerator system for radiation therapy.

CPRIT and COVID-19

The global COVID-19 pandemic profoundly affected CPRIT and its grantees. Like so many other institutions across the country, CPRIT grantees paused clinical trial enrollment, cancer screenings, vaccinations, and frontline cancer prevention education efforts. Unfortunately and unavoidably, there was a 60% decrease in CPRIT-funded prevention services from March 1 to August 31, 2020 compared to September 1, 2019 to February 29, 2020. However, despite unavoidable challenges, CPRIT grantees found ways to continue critical cancer research and prevention efforts. Below are two examples of CPRIT grantees finding ways to continue their research and provide prevention services.

Dr. Abbey Berenson, Director of The University of Texas Medical Branch at Galveston Center for Interdisciplinary Research in Women's Health developed a continuation plan for her CPRIT-supported clinical trial at UTMB when COVID-19 closures and protocols threatened to pause enrollment and stop work. Dr. Berenson's plan included patient visits in two designated clinics and curbside vaccinations that resulted in approximately 300 study visits between March 2 to September 30, 2020. Dr. Berenson was also able to enroll 87 new trial participants once UTMB allowed researchers to resume new enrollment for clinical trials on May 29, 2020.

The Breast Screening and Patient Navigation (BSPAN) project directed by Dr. Simon Lee at The University of Texas Southwestern Medical Center, temporarily stopped mammography and follow up services in rural and underserved counties in North Texas. When BSPAN was able to resume June 1, it instituted new safety precautions for patients and staff including longer appointment times, required masking, full personal protective equipment for staff, cleaning/sanitization between appointments, and visitor restrictions. Because large in-person public events are not an option, the BSPAN outreach team now focuses on mailings and virtual and digital methods to promote the screenings. As a result of resuming prevention services with these heightened protections, BSPAN screenings are at or near capacity and the project provided first-time mammograms to 181 women.

Conclusion

CPRIT's three programs show merit and progress and should continue operations. The work conducted under the purview of CPRIT's programs is part of an iterative cycle with observations emerging from the laboratory making their way to the public and back again to the laboratory. Essential players in this cycle are basic scientists, physician scientists, clinical researchers, product development entrepreneurs, public health professionals, health care providers, patients, community organizations, early-stage companies, and research institutions across Texas. Through CPRIT's programs the state is investing in intellectual and research support

infrastructure that is attracting, creating and expanding research capabilities of Texas institutions of higher education and the Texas life science industry, expediting innovation, and increasing the likelihood of breakthroughs in cancer prevention and cures.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT: CPRIT ACTIVITIES UPDATE FOR NOVEMBER AND DECEMBER
DATE: DECEMBER 23, 2020

Topics in this memo include CPRIT activities in November and December as well as recent milestones in our fight against cancer, a staffing summary, outreach efforts, a pre-legislative session update and news from Compliance, Programs, and Operations.

On behalf of everyone at CPRIT, we hope that you and your families have a happy and healthy holiday season. We look forward to an exciting and rewarding 2021.

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- In an interview that aired October 30, 2020, Izi Obokhare, M.D, FACS, FICS, Texas Tech University Health Sciences Center surgeon discussed the impact of the COVID-19 pandemic on cancer screenings in the Amarillo area. Dr. Obokhare is the Project Director of Get FIT to Stay Fit: Stepping Up to Fight Colorectal Cancer in the Panhandle (PP180031) serving 26 rural counties. He reports that since the pandemic, he has seen a 70 - 75 percent decrease in people coming in to get screened, explaining, “It’s crucial to catch problems early, especially cancer. When someone is diagnosed at an early stage, like stage one cancer, the prognosis is much better, and the cure rate is better.”
<https://www.newschannel10.com/2020/10/30/cancer-screening-down-amarillo-cancer-deaths-predicted-rise-due-covid/>
- The V Foundation for Cancer Research awarded CPRIT Scholar Sam McBrayer, Ph.D., a V Scholar Grant to study glioma. The grant, announced November 10, supports young tenure-track faculty early in their cancer-research careers and will provide Dr. McBrayer with \$200,000 over two years. Dr. McBrayer, assistant professor of Pediatrics at The University of Texas Southwestern Medical Center, also received the 2020 Abeloff V Scholar Grant for having the highest-rated V Scholar proposal this year. Basketball coach Jim Valvano founded the V Foundation for Cancer Research with a single goal – to achieve Victory over cancer. Dr. McBrayer was a post-doctoral fellow with 2019 Nobel Laureate William Kaelin at the Dana Farber Cancer Institute when UT Southwestern recruited him in 2019 to join the faculty of the Children’s Medical Center Research Institute (RR190034).

- On December 3 *Forbes* named Julian West, Ph.D., a CPRIT Scholar and assistant professor of chemistry at Rice University, to the 10th annual [Forbes 30 Under 30](#), a gathering of people under 30 years old it considers the “brightest young entrepreneurs, innovators and game-changers.” Rice recruited Dr. West in 2019 from the California Institute of Technology with the backing of a First Time Tenure Track CPRIT recruitment award. His chemical synthesis lab develops bioactive molecules through creative advances in catalysis, with a particular focus on precursor molecules that will ease the design and manufacture of anti-cancer drugs.
- Jason McLellan, Ph.D., an associate professor in the Department of Molecular Biosciences at The University of Texas at Austin, and Daniel Wrapp, a graduate student fellow, were among seven winners of this year’s Golden Goose Award. Announced on December 1, the award recognizes their contributions leading to the development of promising vaccines, antibody treatments, and other efforts to thwart COVID-19. Dr. McLellan and Mr. Wrapp, along with a team at the NIH Vaccine Research Center, identified the COVID-19 stabilized spike protein used as the antigen in the Pfizer and Moderna vaccines. The UT Austin team also earned praise for their studies with scientists in Belgium that engineered an antibody produced by llamas for use in fighting COVID-19. Dr. McLellan’s research required use of the UT Austin Sauer Structural Biology Laboratory, a core facility funded in part by CPRIT.

Representative Jim Cooper of Tennessee envisioned the Golden Goose Award to recognize the tremendous human and economic benefits of federally funded research. The award, first given in 2012, highlights examples of seemingly obscure studies that have led to major breakthroughs and resulted in significant societal impact. The Golden Goose Award has been under the stewardship of the American Association for the Advancement of Science since 2017.

- On December 9 ImmunoGenesis, Inc. announced it acquired the rights to a drug known as evofosfamide, a hypoxia-reducing agent. The company plans to initiate a Phase 2 clinical trial in 2021 investigating evofosfamide in combination with both CTLA-4 and PD-1 blockade in patients with castration-resistant prostate cancer, pancreatic ductal adenocarcinoma, and HPV-negative head and neck cancer. Houston-based ImmunoGenesis, received a \$15.4 million CPRIT Product Development award in 2020 to fund the development of a novel immunotherapy drug active across immune “hot” and “cold” cancers
- OncoNano Medicine, Inc. reported positive results from its preclinical study of ONM-400, a novel interleukin-2 (IL-2) encapsulating pH-activated nanoparticle that targets metabolic acidosis of cancer. The data, presented on November 9 at the Society for Immunotherapy of Cancer 35th Anniversary Annual Meeting, demonstrate successful tumor acidosis-driven accumulation that provides a high local concentration of IL-2 within tumors potentially resulting in an improved therapeutic index for this cancer therapeutic.

The Southlake-based company is raising \$60 million in new funding as of November 13. Interim CEO Alvaro Guillem played a key role in securing recent investment to support aggressively expanding the company, as well as broaden and accelerate product

development. CPRIT has awarded three Product Development awards to OncoNano. Two awards (\$6.0 million in 2014 and \$10.0 million in 2020) support the company's development of ONM-100 to detect breast, head and neck, and skin cancers. The third award, totaling \$15.4 million and approved in 2019, funds the development of a novel T-cell activating cancer vaccine for solid tumors.

- On December 14 Hummingbird Bioscience, Inc. announced a collaboration with Tempus, Inc. to harness AI-driven precision medicine to accelerate clinical development of Hummingbird's lead clinical program, HMBD-001 in HER3 driven cancers including NRG1-fusions. The company, which has offices in Houston, South San Francisco, and Singapore, received a \$13.1 million CPRIT Product Development award in 2019 to fund the development of a first-in-class anti-VISTA monoclonal antibody for the treatment of MDSC-mediated suppression of anti-tumor immunity in solid tumors and lymphomas. VISTA (V-domain Ig Suppressor of T cell Activation) is a co-inhibitory immune checkpoint receptor of the B7 family that suppresses T-cell activity and plays a critical role in the formation of tumors and resistance to immunotherapy in cancer.
- Allterum Therapeutics, Inc. completed a \$1.8 million Series Seed offering to members of the FanninDirect investor group on December 17. The Houston-based company also named Philip Breitfeld, MD, as Allterum's Chief Medical Officer. Dr. Breitfeld is a pediatric oncologist and former Global Vice President, Therapeutic Centers of Excellence of IQVIA (the renamed Quintiles/IMS Health). Allterum received a \$2.9 million CPRIT Product Development SEED award in 2019 to develop a novel immunotherapy to treat IL7R-expressing cancers, including difficult to treat cases of pediatric acute lymphoblastic leukemia.

Notable CPRIT-Supported Research Accomplishments

- Livia Eberlin, Ph.D., assistant professor of Chemistry at The University of Texas at Austin, reported in the November edition of the journal *Clinical Chemistry* on use of desorption electrospray ionization mass spectrometry imaging (DESI-MSI) to distinguish between different histologic subtypes of lung cancers in a minimally invasive fine needle aspiration (FNA) biopsy. The ability to use DESI-MSI to analyze small tissue samples is important because clinicians are increasingly using FNA biopsies for lung cancer diagnosis and subtyping. A CPRIT Individual Investigator Research Award supported Dr. Eberlin's research (RR160776).
- About half of all cancers have mutations of the gene p53, normally responsible for warding off cancer. Scientists at The University of Texas Southwestern Medical Center have discovered a new role for p53 in its fight against tumors - preventing retrotransposons, or "jumping genes," from hopping around the human genome. Retrotransposons are stretches of DNA that can insert themselves into new spots in the genome. Scientists consider these mobile genetic elements beneficial to some degree because they can help genes evolve with new functions. However, the jumping genes also have the potential to shuffle genomes and

insert themselves into genes that are critical for cell health and growth, potentially contributing to cancer.

A team led by John Abrams, Ph.D., professor of cell biology at UT Southwestern, found that retrotransposons move and multiply more than usual in cells with missing or mutated p53. The finding, published in the November 1 issue of the journal *Genes & Development*, suggests that one way in which p53 works to prevent cancer is by blocking retrotransposons from leading to other cancer-causing mutations. Dr. Abrams' team also showed that a drug blocking the ability of retrotransposons to copy themselves prevented inflammation otherwise seen in cells with elevated levels of retrotransposon movement. More work will help determine whether a drug targeting retrotransposon could slow or stop the growth of existing cancers. A CPRIT Individual Investigator Research Award to Dr. Abrams supported this work. (RP170086).

- Immatics N.V. presented Phase 1 results from their ACTolog program IMA101 at the 35th Annual Society for Immunotherapy of Cancer Meeting, held virtually November 9-14. ACTolog is a pilot study for a personalized multi-TCR-T approach to address challenges for effective cancer immunotherapy, such as tumor heterogeneity and tumor immune escape. The company's data demonstrate the feasibility of the approach while also showing that patients tolerate the therapy. In addition, case studies within the treated patient population support further exploration of a personalized ACT approach using potent high-affinity TCRs. Houston-based Immatics US, Inc. received a \$19.7 million CPRIT Product Development award in 2015 to develop personalized cellular therapies targeting multiple cancer types.
- Medicenna Therapeutics Corp. presented updated data from a Phase 2b trial evaluating MDNA in recurrent glioblastoma patients, as well as an overview of a planned MDNA55 Phase 3 registration trial at the 2nd Annual Glioblastoma Drug Development Summit on December 10. The company, with its U.S. headquarters in Houston, will use an innovative open-label hybrid design to allow use of matched external control for two-thirds of the Phase 3 trial's control arm. The company expects the design to accelerate trial timelines and reduce costs compared with a traditional randomized control trial. Medicenna received a \$14.1 million CPRIT Product Development award in 2014 to support the development of a novel immunotherapy treatment for recurrent glioblastoma and other brain cancers.
- Aravive, Inc. announced November 19 that the company has received guidance from the U.S. Food and Drug Administration (FDA) on a Phase 3 trial design for AVB-500 in platinum resistant ovarian cancer. The global, randomized, double-blind, placebo-controlled adaptive trial will evaluate efficacy and tolerability of AVB-500 at a dose of 15 mg/kg in combination with paclitaxel. The company plans to initiate the trial in the first quarter of 2021, with an interim analysis expected a year later. Houston-based Aravive received a \$20 million CPRIT Product Development award in 2015 to fund the development of AVB-500, an engineered AXL decoy receptor for the treatment of ovarian cancer.

Personnel

CPRIT has filled 34 of our 36 full-time equivalent (FTE) positions.

CPRIT Outreach

Staff outreach activities during November and December include:

- Chief Scientific Officer Dr. Jim Willson was a featured speaker at the 2020 American Cancer Society Cancer Action Network Texas Forum Series: Cancer Research Beyond COVID-19 on November 5. Several CPRIT staff also attended the virtual forum.
- Chief Product Development Officer Dr. Cindy WalkerPeach made a presentation on CPRIT and the Product Development Program at the virtual Texas Life Science Venture Forum. Senior Program Manager for Product Development Rosemary French also attended the November 10-12 event hosted by BIO Houston and the Rice Alliance for Technology and Entrepreneurship.
- Chief Prevention Officer Ramona Magid attended the virtual National Colorectal Cancer Roundtable 2020 “80% in Every Community” Conference & Annual Meeting on November 16-17.
- Ms. French attended the ATI Healthcare Companies Demo Day, a virtual event hosted by the Austin Technology Incubator at The University of Texas at Austin on November 16.
- Ms. Magid attended the virtual Texas HPV Coalition annual meeting November 17-20.
- On November 19 Dr. Cindy WalkerPeach and Ms. French attended the Big Idea Competition, a virtual event hosted by The University of Texas at Dallas.
- Dr. WalkerPeach and Ms. French provided a presentation on CPRIT and the Product Development Program at the virtual “Launch and Learn: A Diverse Life Science Career” hosted by the Temple Health and Bioscience District on December 4.
- Dr. Wilson and Dr. WalkerPeach were panelists at the Brazos Valley Economic Developments Corporation’s Webinar “Funding Opportunities with CPRIT Supporting the Brazos Valley Life Science Industry” on December 8.
- Dr. WalkerPeach presented at the Life Science Innovation Tour: Connecting the Dots Across Texas, a virtual event hosted by Texas Healthcare and Bioscience Institute on December 9.
- Dr. WalkerPeach and Ms. French attended the virtual summit “Biomedical Manufacturing on the Border: Economic and Industry Trends” hosted by BIO El Paso Juarez on December 15.

- Senior Program Manager for Academic Research Dr. Patty Moore represented CPRIT on the Governor’s Commission of Women, the State Agency Council and Partnership for Children’s Holiday Wishes Project for Texas children in foster care. Through the generosity of CPRIT staff and other state agencies, the project was able to fulfill the holiday wishes for over 2,700 Texas children in foster care.

Legislative Session Activities and Outreach

The 87th Texas Legislature convenes at noon on January 12, 2021, and adjourns *Sine Die* at midnight May 31, 2021. In preparation for the upcoming session, CPRIT staff activities and outreach include:

- On November 2 Chief Operating Office Heidi McConnell, Deputy Executive Officer and General Counsel Kristen Doyle and I briefed staff of the House Committee on Appropriations by teleconference on CPRIT’s Request for Legislative Appropriations for Fiscal Biennium 2022-23.
- Ms. McConnell, Ms. Doyle and I presented by videoconference CPRIT’s Request for Legislative Appropriations for Fiscal Biennium 2022-23 on November 6 in the statutorily required public hearing to the staffs of the Governor’s Office and Legislative Budget Board.
- On December 15 I briefed staff of presumptive Speaker of the House Dade Phelan on CPRIT activities by teleconference.

Compliance Program Update

Submission Status of Required Grant Recipient Reports

CPRIT has \$1.4 billion in active grants under management, with 560+ grants that are either active or wrapping up grant activities. We receive an average of 560 grantee reports each month. As of December 16, four entities had not filed four Academic Research reports and three Product Development Research reports. CPRIT’s grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

Financial Status Report Reviews

CPRIT’s compliance specialists performed 307 second-level reviews of grantee Financial Status Reports (FSRs) for the month of November and December. Thirty-four FSRs (11%) required resubmission due to insufficient or inaccurate documentation submitted by the grantee. CPRIT’s grant accounting staff completes the initial review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Single Audit Tracking

Compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend \$750,000 or more in state awards in the grantee's fiscal year must submit a single independent audit, a program specific audit, or an agreed upon procedures engagement. The grantee submits the independent audit report with findings to CPRIT within 30 days of receipt, but no later than nine months after the grantee's fiscal year end.

Currently, all grantees have submitted required audits. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan unless the grantee requests additional time by the due date of the required audit and CPRIT's CEO approves the request.

Desk Reviews

Compliance specialists performed four enhanced desk-based financial monitoring reviews for October. Enhanced desk reviews verify that grantees expend funds in compliance with specific grant requirements and guidelines and may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Compliance specialists are working with one grantee to remediate desk review findings.

Onsite Reviews

CPRIT completed four virtual onsite reviews in November and December. Onsite reviews examine the grantee's financial and administrative operations, subcontract monitoring, inventory procedures, procurement and contracting procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance. Compliance specialists are working with one grantee to remediate onsite review findings.

Annual Compliance Attestation

CPRIT requires grantees to submit an annual Attestation Form, demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, grant contract terms, and the Uniform Grant Management Standards. This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows compliance specialists to work proactively with grantees towards full compliance prior to a desk review or on-site review. As of December 16, 18 grantees have submitted their annual Compliance Attestations. Compliance staff are working with the remaining grantees to submit their Attestation prior to the December 31 deadline.

Training and Support

CPRIT staff conducted two new Authorized Signing Official (ASO) training webinars in November and December for Baylor University and University of North Texas Health Science

Center at Fort Worth. The training covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, CPRIT requires new ASOs to complete a compliance training within 60 days of the change

Academic Research Program Update

FY 2021 Recruitment Applications

CPRIT’s Scientific Review Council (SRC) met December 10 to review recruitment applications submitted for cycles 21.04 and 21.05. Dr. Willson will present the SRC’s recruitment recommendations for the second quarter of FY 2021 to the Program Integration Committee and the Oversight Committee in February 2021.

FY 21.04 and 21.05 Mechanism	Received	Funds Requested	Approved by SRC	Funds Approved
Recruitment Established Investigators	3	\$18,000,000	2	\$12,000,000
Recruitment of Rising Stars	1	\$4,000,000	0	N/A
Recruitment of First-Time, Tenure Track Faculty Members	0	N/A	0	N/A
TOTAL	4	\$22,000,000	2	\$12,000,000

FY 2021 Requests For Applications (RFAs)

In addition to three FY 2021 recruitment RFAs and the Research Training Award RFA published in late June, CPRIT released six academic research RFAs in early August. CPRIT accepted training award applications July 8 through October 28. Peer review of the training applications will take place in Spring 2021 and Dr. Willson will present the SRC’s training award recommendations to the Program Integration Committee and the Oversight Committee in May 2021. CPRIT began accepting applications for the other FY 2021 research awards September 16. Applicants may submit proposals through January 27, 2021. After peer review, Dr. Willson will present the SRC’s recommended research awards to the Program Integration Committee and the Oversight Committee for consideration in August 2021.

Product Development Research Program Update

FY 2021 Product Development Research RFAs

CPRIT released three Product Development RFAs on November 9 that seek applications for the Texas Company, Relocation Company, and Seed Company awards. Dr. WalkerPeach and Ms. French hosted a webinar for potential applicants on November 19. CPRIT started accepting proposals on December 2 and will continue through January 27, 2021. Dr. WalkerPeach will

present the Product Development Review Council's award recommendations to the Program Integration Committee and the Oversight Committee in August 2021.

Prevention Program Update

FY 2021 Cycle 1 (21.1) Prevention Review Cycle

CPRIT released the *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations* RFA on August 3 for the first review cycle of FY 2021. Applicants submitted 12 applications by the October 5 deadline, requesting \$26,133,587 in grant funds. Peer review will occur January 19-20, 2021, by teleconference. Ms. Magid will present the Prevention Review Council's (PRC) 21.1 recommendations to the Program Integration Committee and the Oversight Committee in May 2021.

FY 2021 Cycle 2 (21.2) Prevention RFAs

The Oversight Committee approved four 21.2 RFAs, which CPRIT released on October 16. Applications are due on February 10, 2021. CPRIT has scheduled peer review for April 26-29, 2021. Ms. Magid will present the PRC's 21.2 recommendations to the PIC and the Oversight Committee in August 2021.

FY 2021 Prevention Program RFAs

- *Dissemination of CPRIT-Funded Cancer Control Interventions*
Seeks to fund projects that will facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based cancer prevention and control interventions across Texas. The proposed project should be able to develop one or more "products" based on the results of the CPRIT-funded intervention. The proposed project should also identify and assist others to prepare to implement the intervention and/or prepare for grant funding.
Award: Maximum of \$300,000 over 24 months.
- *Evidence-Based Cancer Prevention Services*
Seeks projects that will deliver evidence-based cancer prevention and control clinical services. CPRIT will give priority to projects that propose to address CPRIT areas of emphasis and serve areas of the state not well addressed by current CPRIT funded projects.
Award: Up to \$1 million over 36 months.
- *Tobacco Control and Lung Cancer Screening*
Seeks programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs across the state, thereby providing greater access for underserved populations and reducing the incidence and mortality rates of tobacco-related cancers. This RFA seeks to promote and deliver evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth.
New Award: Up to \$1 million over 36 months.

Expansion Award: Up to \$2.5 million over 3 years.

- *Dissemination of CPRIT-Funded Cancer Control Interventions*
Seeks to fund projects that will facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based cancer prevention and control interventions across Texas. The proposed project should be able to develop one or more "products" based on the results of the CPRIT-funded intervention. The proposed project should also identify and assist others to prepare to implement the intervention and/or prepare for grant funding.
Award: Up to \$300,000 over 24 months.
- *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations*
Seeks to support coordination and expansion of evidence-based services to prevent cancer in underserved populations who do not have adequate access to cancer prevention interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community and use evidence-based models shown to work in similar communities to prevent and control these cancers. Currently funded CPRIT projects should propose to expand their programs to include additional types of prevention clinical services and/or an expansion of current clinical services into additional counties. In either case, the expansion must include delivery of services to nonmetropolitan and medically underserved counties in the state.
Initial Expansion Award: Up to \$2 million over 3 years.
Subsequent Expansion Award: Up to \$2.5 million over 5 years.
- *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations*
Seeks to support coordination and expansion of evidence-based services to prevent cancer in underserved populations who do not have adequate access to cancer prevention interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community and use evidence-based models shown to work in similar communities to prevent and control these cancers. Currently funded CPRIT projects should propose to expand their programs to include additional types of prevention clinical services and/or an expansion of current clinical services into additional counties. In either case, the expansion must include delivery of services to nonmetropolitan and medically underserved counties in the state.
Initial Expansion Award: Maximum of \$2 million over three years.
Subsequent Expansion Award: Maximum of \$2.5 million over five years.

Operations, Audit and Finance Update

FY 2020 Independent Financial Audit

The Audit Subcommittee met with CPRIT's independent auditor, McConnell & Jones LLP, on December 8 to review the audit report of CPRIT's financial statements for FY 2020. The McConnell & Jones audit team did not identify any material weaknesses, significant deficiencies

or compliance issues in the report. The Audit Subcommittee accepted the audit report and CPRIT staff submitted it to Office of the Comptroller of Public Accounts, State Auditor's Office, Governor's Office, Legislative Budget Board and other legislative offices as required. We have also posted the report on CPRIT's website.

Upcoming Request for Proposals for Grant Management Support Services

CPRIT will issue a competitive request for proposals (RFP) for grant management support services in late winter 2021 to continue these services for FY 2022 and beyond. CPRIT exercised its last renewal option for the contract with GDIT for FY 2021, ending on August 31, 2021. Because the contract exceeds \$5 million the state's Contract Advisory Team (CAT) must review the RFP documents for risk mitigation before CPRIT can publish the RFP solicitation publicly. The CAT review will take at least 30 days.

Grant Expenses Related to COVID-19

In November CPRIT grant accounting and compliance staff processed and paid 54 FSRs for the March-May reporting period. In the group paid in November, ten grant FSRs from three different grant organizations reported COVID-related expenses incurred during the March-May quarterly reporting period totaling \$278,508. Of those ten grant FSRs, eight submitted \$261,211 of personnel/fringe expenses for employees who could not work or worked at reduced level due to COVID closures and two grants submitted \$622 in cancelled travel expenses.

In addition, one grant FSR for the June-August quarterly reporting period submitted \$16,675 in other COVID expenses. CPRIT stopped reimbursing grantees for personnel/fringe expenses for employees who could not work or worked at a reduced level after the March-May quarter. However, we continue to allow grantees to claim COVID-related expenses for personal protective equipment and COVID tests if the equipment or tests are necessary for CPRIT-funded clinical services (e.g. cancer screenings or clinical trials).

The 54 grant FSRs processed in November added to the 330 grant FSRs processed in September and October with COVID-related expenses of \$2,635,242. Because CPRIT paid the grant reimbursements on or after September 1, we report these as FY 2021 COVID expenses to the LBB and the Office of the Governor. The FY 2021 expenses are in addition to the \$423,421 in FY 2020 COVID expenses reported on 42 grant FSRs from ten different grant organizations, which CPRIT processed by August 31, 2020.

COVID-related grant expenses reimbursed by CPRIT to date total \$3,337,171.

Communications Update

Media Highlights

- An *Innovation Map* article about the Rice Alliance for Technology and Entrepreneurship also featured three CPRIT-funded companies – Hummingbird Biosciences, ImmunoGenesis, and Perimeter Medical Imaging - as among the ten most promising life science companies.

- KFOX 14 El Paso quoted CPRIT Oversight Committee Presiding Officer Dee Margo about his concerns related to low rates of regional cancer screenings based on CPRIT data.
- *The Scientist* featured CPRIT Scholar Gloria Echeverria, Ph.D. Assistant Professor at Baylor College Medicine as its “Scientist to Watch” for December. *Forbes* named CPRIT Scholar Julian West, Ph.D., Assistant Professor of Chemistry at Rice University to the “Forbes 30 Under 30” list.

11/16/20 – “Houston organization names 10 most promising life sciences startups”- *Innovation Map* <https://houston.innovationmap.com/rice-alliance-biohouston-name-most-promising-life-science-companies-2648936821.html>

11/19/20 – “El Paso prepares to distribute upcoming COVID-19 vaccine”- *KFOX 14 El Paso* <https://kfoxtv.com/news/coronavirus/el-paso-officials-to-update-community-on-covid-19-in-region>

12/1/20 – “Gloria Echeverria Investigates an Insidious Form of Breast Cancer” – *The Scientist Magazine* <https://www.the-scientist.com/scientist-to-watch/gloria-echeverria-investigates-an-insidious-form-of-breast-cancer-68180>

12/3/20 – “Rice chemist, alums named to Forbes 30 Under 30” – *Press Release, Rice University* <http://news.rice.edu/2020/12/03/rice-chemist-alum-named-to-forbes-30-under-30/>

Dr. West’s “Forbes 30 Under 30” profile: <https://www.forbes.com/profile/julian-west/?list=30under30-science&sh=1aafdea14ffc>

Outreach Activities

As noted earlier, Brazos Valley Economic Development Corporation, with assistance from Communications, held a webinar event on December 8 featuring CPRIT funding opportunities and showcasing CPRIT grantees and stakeholders. Participants included research grantees and stakeholders from the Texas A&M System as well as Fujifilm Diosynth. To view a recording of the event, please click on the following link: <https://cprit.us/37ThNC9> (Passcode: b=pAfh^8)

Social Media

November was Lung Cancer Awareness Month and Pancreatic Cancer Awareness Month, with World Pancreatic Cancer Day on November 19. CPRIT highlighted our grantees and initiatives working on these cancer sites via social media content. Social media statistics for the past month are below.

Social Media Statistics

- Twitter (November 20 – December 17)

Total Tweets: 9
Tweet Impressions: 17,400
Profile Visits: 843
Mentions: 47
New Followers: 18 (2,698 total)

Top tweet: Congrats to CPRIT [#Scholar @pushingarrows](#) for being named in [@ForbesUnder30](#)! Dr. West was recruited to [@RiceUniversity](#) in 2019 through a First-Time, Tenure-Track Faculty Member award.

<https://twitter.com/RiceUniversity/status/1334635282759618561>

Impressions: 2,517
Engagements: 33

Top mention: Biochemistry and Molecular Biology, UTMB Galveston [@bmb_utmb](#)
Delighted to share that Dr. Guy Nir [@GuyNir5](#), who will join BMB in January 2021, has been awarded a \$2,000,000 First-Time, Tenure-Track Faculty Members Award from [@CPRITTexas](#) <https://cprit.state.tx.us/news-events/articles/cancer-prevention-research-institute-of-texas-awards-26-million-in-new-recruitment-grants/>
Engagements: 173

- LinkedIn (November 16 – December 16)

Total Updates: 11
Post Impressions: 3,300
Reactions: 79
Shares: 9
Page views: 140
Unique Visitors: 51
New followers: 15 (1087 total)

Top Update: CPRIT [#Scholar](#) Dr. Gloria Echeverria of [Baylor College of Medicine](#) is December's "Scientist To Watch" in [The Scientist](#) for her research into triple negative breast cancer. Dr. Echeverria was recruited to Baylor College of Medicine through a CPRIT First-Time, Tenure-Track Faculty Member award in 2019, where she has since established the Gloria Echeverria Lab. [#TNBC](#) <https://cprit.us/3g3fboW>

Impressions: 538
Clicks: 22
Reactions: 22
Engagement rate: 8.36%

- Facebook (November 19 – December 16)

Reach: 395 people
Engagement: 71 reactions/clicks

Page Views: 152

Top Post: CPRIT announces the release of three Requests for Applications (RFAs) for Product Development grants available to cancer-focused, Texas-based companies or those willing to relocate. The RFAs are Texas Company Product Development Research Awards (TXCO), Company Relocation Product Development Research Awards (RELCO), and Seed Awards for Product Development Research (SEED). The application period for the [#TXCO](#), [#RELCO](#) and [#SEED](#) funding opportunities is December 2, 2020, through January 27, 2021. Complete RFAs detailing deadlines, requirements and instructions are available in the Apply for Funding section of CPRIT’s website: <https://cprit.us/2XiUaPu>

Post Reach: 159 people

Engagement: 4 clicks, 5 reactions

Upcoming Subcommittee Meetings

Listed below are the subcommittee meetings in advance of the February 17, 2021, Oversight Committee meeting.

Board Governance	February 4 at 10:00 a.m.
Audit	February 8 at 10:00 a.m.
Prevention	February 9 at 10:00 a.m.
Academic Research	February 10 at 10:00 a.m.
Product Development	February 11 at 10:00 a.m.
Nominations	February 12 at 10:30 a.m.

We will send instructions for signing onto the Zoom platform along with the subcommittee agenda and meeting materials one week prior to the meeting date. Please plan to join the subcommittee meeting a few minutes early so we can address any technology issues before the meeting start time.

CPRIT has awarded **1,584** grants totaling **\$2.661 billion**

- 244 prevention awards totaling \$277.7 million
- 1,340 academic research and product development research awards totaling \$2.383 billion

Of the \$2.383 billion in academic research and product development research awards,

- 30.6% of the funding (\$730.0 million) supports clinical research projects
- 24.6% of the funding (\$586.0 million) supports translational research projects
- 28.5% of funding (\$679.6 million) supports recruitment awards
- 13.8% of the funding (\$327.7 million) supports discovery stage research projects
- 2.5% of funding (\$60.0 million) supports training programs.

CPRIT has 15 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 6 Academic Research
- 4 Prevention
- 3 Product Development



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT: CPRIT ACTIVITIES UPDATE FOR JANUARY
DATE: FEBRUARY 1, 2021

Topics in this memo include preparations for the upcoming February 17, 2021, Oversight Committee meeting as well as CPRIT activities in January, recent milestones in the fight against cancer, a staffing summary, a legislative update, our 2020 annual report, outreach efforts, a legislative update and news from Compliance, Programs, and Operations.

Planning for the February 17 Oversight Committee Meeting

The Oversight Committee will meet February 17 using the Zoom platform. CPRIT will post the final agenda for the Oversight Committee meeting by February 9. Please notify me if you are unable to attend the February 17 meeting or have schedule constraints that require you to join the meeting after 9:00 a.m. or leave prior to 10:30 a.m. Oversight Committee members will receive an electronic copy of the meeting books by February 10 and mail you hard copies of the meeting books and proposed award packets.

You will receive an email from CPRIT by February 5 with a link and password to access the Program Integration Committee's recruitment award recommendations via the grant award portal. The portal has a summary of the award slate, as well as supporting documentation for each proposed award, including the application, CEO affidavit, summary statement, and grant pedigree. Please allow some time to complete the individual conflict of interest checks and review the supporting material.

You will receive an email from CPRIT with information unique to you for signing onto Zoom. (This is different than the sign-on information provided for the public listed on the published Oversight Committee agenda.) Plan to sign on 15 – 30 minutes before the 9:00 a.m. start time so that we can address any connection issues without delaying the meeting.

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- KVIA ABC 7 El Paso interviewed Dr. Jessica Calderon-Mora of Texas Tech University Health Sciences Center El Paso, co-program director of "Tiempo de Vacunarte (Time to Get

Vaccinated) 2” (PP190058), about the successful project offering no-cost vaccines to residents of El Paso and surrounding counties.

<https://www.youtube.com/watch?v=NsdhaQdIQ-w&feature=youtu.be>

- Aeglea Biotherapeutics, Inc. announced December 17 the appointment of Alison Lawton to its Board of Directors. Ms. Lawton previously served as CEO of Kaleido Biosciences. The Austin-based company received a \$19.8 million CPRIT Product Development Research award in 2014 to support the development of an engineered human arginase targeting multiple cancer types.
- Houston-based Aravive, Inc. announced that Dr. Ray Tabibiazar will be stepping down from the Aravive Board of Directors but will remain an advisor to the company, effective December 31, 2020. This transition allows Dr. Tabibiazar to focus on a new venture. He co-founded Aravive Biologics and served as the chairman of its board of directors and as president and CEO from its inception to April 2017 and as executive chairman from May 2017 until October 2018. During his tenure, he led the Aravive Biologics reverse merger with Versartis, Inc., to form the combined company, Aravive, Inc. The company received a \$20 million CPRIT Product Development Research award in 2015 to fund the development of AVB-500, an engineered AXL decoy receptor for the treatment of ovarian cancer.

Notable CPRIT-Supported Research Accomplishments

- A collaborative research program led by two CPRIT Scholars - Guo-Min Li, Ph.D. and Yang-Xin Fu M.D., Ph.D. - at The University of Texas Southwestern Medical Center shows DNA that ends up where it does not belong in cancer cells can unleash an immune response that makes tumors more susceptible to immunotherapy. The findings, published in the January 11, 2021, edition of *Cancer Cell*, suggest that delivering radiation – which triggers DNA release from cells – before immunotherapy could be an effective way to fight cancers that are challenging to treat by making them susceptible to immunotherapies such as the immune check-point inhibitors. UT Southwestern recruited both Dr. Li, professor of radiation therapy (RR160101), and Dr. Fu, professor of pathology (RR150072), to Texas with CPRIT Established Investigators grants.
- Philip Lupo, Ph.D., associate professor of pediatrics at Baylor College of Medicine, led a multicenter genomic assessment of children with rhabdomyosarcoma (RMS) to determine the prevalence of genetic changes that result in cancer predisposition. The results, published in the December 29, 2020, edition of the *Journal of the National Cancer Institute*, were based on analysis of 615 patients with newly diagnosed RMS from institutions across North America. Rhabdomyosarcoma is a highly malignant tumor and the most common soft tissue sarcoma in children. Despite its clinical significance, less is known about genetic susceptibility to this malignancy compared to other pediatric cancers. The results showed that 7.3% of patients with RMS had clinically significant variant changes in cancer-predisposition genes compared to 1.4% of controls. This work promises to further research examining whether genetic changes impact RMS patient outcomes, including response to therapy, likelihood of relapse, and overall survival. Dr. Lupo received a \$1.5 million CPRIT

Individual Investigator Research Award for Prevention and Early Detection to support this research (RP170071).

- Researchers at The University of Texas Southwestern Medical Center identified a new metabolic vulnerability in an aggressive form of non-small cell lung cancer. They discovered that the hexosamine biosynthesis pathway, responsible for producing a key substrate for protein glycosylation, activates in patients with mutations in two key genes – *KRAS* and *LKBI*. Patients whose tumors contain both mutations have poor outcomes and usually do not respond to immunotherapy. These findings may pave the way for new treatments. CPRIT supported the research, published in the November 30, 2020, edition of *Nature Metabolism*, through a \$6 million Multi-Investigator Research Award (RP160652) and a \$900,000 Individual Investigator Research Awards (RP160089) to Ralph DeBerardinis, M.D. Ph.D., professor of pediatrics at UT Southwestern.
- CPRIT Scholar Bing Zhang, Ph.D., professor in the Department of Molecular and Human Genetics at Baylor College of Medicine, with collaborators at Johns Hopkins University and the National Cancer Institute’s Clinical Proteomic Tumor Analysis Consortium, used proteomic analyses to identify three molecular subtypes in head and neck squamous cell carcinoma. Clinicians may be able to use these three subtypes to better determine appropriate treatment. The research, published in the January 7, 2021, edition of the journal *Cancer Cell*, identified candidate biomarkers to use to match patients to effective therapies or clinical trials. Baylor College of Medicine recruited Dr. Zang to Texas in 2017 from Vanderbilt University School of Medicine with the help of a CPRIT Rising Star Award (RR160027.)

Personnel

CPRIT has filled 34 of our 36 full-time equivalent (FTE) positions.

CPRIT Outreach

Staff outreach activities during January include:

- Senior Program Manager for Academic Research Dr. Patty Moore represented CPRIT in planning a virtual guided tour of a new exhibit at the Bob Bullock Story of Texas Museum, “Not Alone, Working Together to Fight Against Human Trafficking.” The Governor’s Commission of Women and the State Agency Council sponsored the virtual tour.
- Chief Prevention Officer Ramona Magid presented CPRIT’s legislative priorities to The University of Texas MD Anderson Cancer Center Executive Advisory Panel on January 8.
- Chief Product Development Officer Dr. Cindy WalkerPeach presented an overview of CPRIT and the Product Development Research Program’s open RFAs at the virtual *Houston Venture Mentoring Service Meeting* on January 14. Senior Program Manager for Product Development Rosemary French also attended the event.

- Ms. French attended the virtual event *Cell Therapy for Cancer Treatment: The Past, Present, and Future* as part of the JLABS Cancer Symposium Series hosted by the Synapse Life Science Consortium on January 28.

Legislative Session Update

CPRIT Staff Activities and Outreach

Chief Operating Officer Heidi McConnell, Deputy Executive Officer and General Counsel Kristen Doyle and I briefed Representative Donna Howard and her staff January 18 by video conference about CPRIT’s Request for Legislative Appropriations for Fiscal Biennium 2022-23.

Senate and House Committee Assignments and Upcoming Hearings

Lieutenant Governor Patrick announced his standing committee assignments for the 87th Texas Legislature. Senator Jane Nelson again chairs the Senate Committee on Finance and Senator Lois Kolkhorst chairs the Senate Committee on Health and Human Services. I will update you when Speaker Phelan announces the House standing committee assignments.

The Senate Committee on Finance set CPRIT’s budget hearing for February 9. Although the House Committee on Appropriations has not announced hearing dates, I expect that CPRIT’s hearing may occur the same week as the Senate Finance hearing. I will keep you updated.

General Appropriations Bills

The House and Senate (Senate Bill 1) released the bills January 21. Both provide CPRIT’s full, constitutionally authorized annual appropriation of \$300 million less the required transfer of \$3.1 million per year to the Cancer Registry at the Texas Department of State Health Services. The table below compares the House and Senate versions related to CPRIT’s budget requests.

Item	House	Senate
Base Adjustment for Ongoing Operating Costs	No	Yes
8 Full-Time Equivalent Positions	No	Yes
Transfer Authority	Yes, partial	Yes
Chief Scientific Officer Exempt Salary Increase	No	No

It is notable that the Senate bill provides all CPRIT’s requested items except the 10% Chief Scientific Officer exempt salary increase. It is rare for an introduced appropriations bill to include most of an agency’s significant requests. This is a definite sign of confidence in CPRIT.

Unfortunately, CPRIT now must amend our request for legislative appropriations by \$450,000 per year for a new exceptional item. The Comptroller Office’s notified CPRIT in early January of an 551% increase in CPRIT’s fiscal year 2020 Statewide Cost Allocation Plan (SWCAP) amount. The SWCAP escalation was a shock. The fiscal year 2020 SWCAP is based on state expenditures and state agencies’ use of central state services in fiscal year 2018. CPRIT began

using the state's CAPP's Financial module for our accounting and procurement processes in fiscal year 2018. CPRIT will continue to use the CAPP's module so we must plan for CPRIT's new, higher SWCAP allocation remaining at this increased level going forward.

CPRIT can accommodate the increased SWCAP cost in our fiscal year 2021 budget because we anticipate having some unused budget in categories such as travel due to the ongoing effects of the pandemic. However, we cannot absorb this expense in our budget going forward without a transfer from research and prevention programs.

- *Base Adjustment for Ongoing Operating Costs*

The Senate bill incorporates CPRIT's requested adjustments except the SWCAP charge described above for ongoing operating costs. The House bill provides a "base" (carryforward of previous appropriations amounts with minimal adjustments mandated in the budget instructions) that the House Committee on Appropriations will use to mark up in subcommittees. This is a more traditional approach to an agency's budget request than the Senate's bill. Unlike many state agencies, state leadership did not instruct CPRIT to make any reductions from its base request for 2022 and 2023.

- *Budget Transfer Authority*

Currently, the Legislative Budget Board (specifically the Chairs of House Appropriations and Senate Finance, the Lieutenant Governor, and the Speaker) must each individually approve a CPRIT transfer request before the agency may transfer appropriated funds between budget line items. These transfer requests are generally routine and non-controversial but necessary to maintain operational stability. However, because of the multiple signoffs required for approval, CPRIT's budget transfer requests have languished administratively for months, with our most recent request taking more than 115 days to receive approval.

The Senate's budget proposal, which tracks our request, authorizes CPRIT's CEO, with Oversight Committee approval, to transfer up to 20 percent from one line item to another. Although CPRIT must report the transfer to the LBB, the Senate version does not require additional approval before the transfer may occur. This is the standard budget transfer provision for most state agencies.

The House's version takes a different approach. It proposes limiting the window for rejecting CPRIT's budget transfer request to 30 days. Unless the House Appropriations Chair, Senate Finance Chair, the Lieutenant Governor or the Speaker specifically reject CPRIT's request, CPRIT may make the budget transfer on the 31st day. The House's proposed change is a significant improvement over CPRIT's current provision, but still treats CPRIT differently from most state agencies.

- *CSO Exempt Salary Increase*

The legislature typically addresses exempt salaries in the last days of the budget conference committee in May. We will continue to work with the Senate and the House to explain the rationale for the salary increase.

Notable Legislation

- SB 71 - Senator Borris Miles filed legislation amending CPRIT's statute (Tex. Health & Safety Code §102.255(d)) to allow research institutions or their affiliated centers to use the federal indirect rate as a credit to offset CPRIT's matching requirement. The credit is already available to institutions of higher education as defined by the Texas Education Code, but the amendment addresses the research institutions that do not qualify under Education Code designation.
- SJR 17 and SB 264 - Senator Jose Menéndez filed legislation to create the Texas Research Consortium to Cure Infectious Diseases (TRANSCEND) with a \$3 billion constitutional bond authorization. Senator Menéndez has explained that he intends CPRIT to serve as a model for the new agency.

I am also aware of legislative interest in developing a brain disease initiative based on CPRIT. We should be proud that legislators consider what CPRIT is doing as a model for other historic state research initiatives.

CPRIT's Fiscal Year 2020 Annual Report

CPRIT released the *Cancer Prevention and Research Institute's 2020 Annual Report* January 31. You can access the report on CPRIT's website (www.cprit.texas.gov) or through this link: <https://2020annualreport.cprit.texas.gov>.

Although CPRIT prepares an annual report every year in accordance with Texas Health and Safety Code § 102.052, this is the first time that CPRIT presents the annual report exclusively through an online platform. The new format provides opportunities for greater insight into CPRIT's statutory mission, our priorities, and the economic and social burden that cancer costs the state. We feature more than 100 CPRIT projects representing 48 different grantee institutions, organizations and companies to illustrate how CPRIT is fulfilling its mission and addressing Oversight Committee priorities. In recognition of the unprecedented challenges posed by the COVID-19 pandemic, the report also includes a section with examples showing the cancer community's response and CPRIT-funded cancer research and instruments that helped advance COVID-19 treatments.

Compliance Program Update

Submission Status of Required Grant Recipient Reports

CPRIT has \$1.4 billion in active grants under management, with 560+ grants that are either active or wrapping up grant activities. We receive an average of 560 grantee reports each month. As of December 21, 11 entities had not filed 20 Academic Research reports and 7 Product Development Research reports. CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

Financial Status Report Reviews

CPRIT's compliance specialists performed 87 second-level reviews of grantee Financial Status Reports (FSRs) in January. Sixteen FSRs (18%) required resubmission due to insufficient or inaccurate documentation submitted by the grantee. CPRIT's grant accounting staff completes the initial review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Single Audit Tracking

Compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend \$750,000 or more in state awards in the grantee's fiscal year must submit a single independent audit, a program specific audit, or an agreed upon procedures engagement. The grantee submits the independent audit report with findings to CPRIT within 30 days of receipt, but no later than nine months after the grantee's fiscal year end.

Currently, all grantees have submitted required audits. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan unless the grantee requests additional time by the due date of the required audit and CPRIT's CEO approves the request.

Desk Reviews

Compliance specialists performed four enhanced desk-based financial monitoring reviews for January. Enhanced desk reviews verify that grantees expend funds in compliance with specific grant requirements and guidelines and may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission.

Onsite Reviews

CPRIT completed four virtual onsite reviews in January. Onsite reviews examine the grantee’s financial and administrative operations, subcontract monitoring, inventory procedures, procurement and contracting procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance. Compliance specialists are working with one grantee to remediate onsite review findings.

Annual Compliance Attestation

CPRIT requires grantees to submit an annual “Attestation Form,” demonstrating compliance with statutory and administrative grant requirements, CPRIT’s policies and procedures, grant contract terms, and the Uniform Grant Management Standards. This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows compliance specialists to work proactively with grantees towards full compliance prior to a desk review or on-site review. As of January 21, two grantees have not submitted their annual compliance attestations. Compliance staff is working with the grantees to address the delay and submit their attestation as soon as possible.

Training and Support

CPRIT staff conducted one new grantee training webinar in January for Invectys USA. The training covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, CPRIT requires new grantees to complete the initial compliance training program prior to receiving disbursement of grant award funds.

Academic Research Program Update

FY 2021 Recruitment Applications

CPRIT’s Scientific Review Council (SRC) met December 10 to review recruitment applications submitted for cycles 21.04 and 21.05. Dr. Willson will present the SRC’s recommendations to the Program Integration Committee (PIC) and the Oversight Committee in February.

FY 21.04 and 21.05 Mechanism	Received	Funds Requested	Approved by SRC	Funds Approved
Recruitment Established Investigators	3	\$18,000,000	2	\$12,000,000
Recruitment of Rising Stars	1	\$4,000,000	0	N/A
Recruitment of First-Time, Tenure Track Faculty Members	0	N/A	0	N/A
TOTAL	4	\$22,000,000	2	\$12,000,000

FY 2021 Review Cycle 1 - Training Applications

CPRIT received 15 applications for research training awards by the October 28, 2020, deadline. Peer reviewers will meet virtually on February 18 to evaluate the applications. Dr. Willson will present the SRC's recommendations to PIC and the Oversight Committee in May.

FY 2021 Review Cycle 2 (21.2)

CPRIT released six academic research RFAs in early August and began accepting applications for the 21.2 review cycle September 16, 2020. In addition to Core Facility Support Awards, High Impact/High Risk Awards, and Early Clinical Investigator Awards, the 21.2 review cycle includes several new RFAs, including the new Clinical Trials Network Award, Texas Clinical Trials Participation Program Award, and Texas Regional Excellence in Cancer Award. Applicants submitted 158 proposals by the January 27 deadline. After peer review, Dr. Willson will present the SRC's recommended research awards to the PIC and the Oversight Committee for consideration in August.

Product Development Research Program Update

FY 2021 Product Development Research RFAs

CPRIT released three Product Development RFAs on November 9 seeking applications for the Texas Company, Relocation Company, and Seed Company awards. Dr. WalkerPeach and Ms. French hosted a webinar for potential applicants on November 19. CPRIT received 35 applications by the January 27 deadline. Dr. WalkerPeach will present the Product Development Review Council's award recommendations to the PIC and the Oversight Committee in August.

Prevention Program Update

FY 2021 Cycle 1 (21.1) Prevention Review Cycle

CPRIT released the *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations* RFA on August 3 for the first review cycle of FY 2021. CPRIT's prevention peer review panel met by videoconference on January 19 to review the 12 applications requesting \$26,133,587 in grant funds. Ms. Magid will present the Prevention Review Council's (PRC) 21.1 recommendations to the PIC and the Oversight Committee in May.

FY 2021 Cycle 2 (21.2) Prevention RFAs

CPRIT released four 21.2 RFAs (listed below) October 16, 2020. Applications are due February 10. CPRIT has scheduled peer review for April 26-29. Ms. Magid will present the PRC's 21.2 recommendations to the PIC and the Oversight Committee in August.

FY 2021 Prevention Program RFAs

- *Dissemination of CPRIT-Funded Cancer Control Interventions*
Seeks to fund projects that will facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based cancer prevention and control interventions across Texas. The proposed project should be able to develop one or more "products" based on the results of the CPRIT-funded intervention. The proposed project should also identify and assist others to prepare to implement the intervention and/or prepare for grant funding.
Award: Maximum of \$300,000 over 24 months.
- *Evidence-Based Cancer Prevention Services*
Seeks projects that will deliver evidence-based cancer prevention and control clinical services. CPRIT will give priority to projects that propose to address CPRIT areas of emphasis and serve areas of the state not well addressed by current CPRIT funded projects.
Award: Up to \$1 million over 36 months.
- *Tobacco Control and Lung Cancer Screening*
Seeks programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs across the state, thereby providing greater access for underserved populations and reducing the incidence and mortality rates of tobacco-related cancers. This RFA seeks to promote and deliver evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth.
New Award: Up to \$1 million over 36 months.
Expansion Award: Up to \$2.5 million over 3 years.
- *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations*
Seeks to support coordination and expansion of evidence-based services to prevent cancer in underserved populations who do not have adequate access to cancer prevention interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community and use evidence-based models shown to work in similar communities to prevent and control these cancers. Currently funded CPRIT projects should propose to expand their programs to include additional types of prevention clinical services and/or an expansion of current clinical services into additional counties. In either case, the expansion must include delivery of services to nonmetropolitan and medically underserved counties in the state.
Initial Expansion Award: Up to \$2 million over 3 years.
Subsequent Expansion Award: Up to \$2.5 million over 5 years.

Operations, Audit and Finance Update

State Auditor's Office Audit

The State Auditor's Office (SAO) notified CPRIT on January 4 that they plan to conduct an audit of grant management at CPRIT. Ms. McConnell, Ms. Doyle, Mr. Burgess, Operations Manager Lisa Nelson and I met with the SAO audit team in an entrance conference on January 11. The SAO audit team is in the planning phase of the audit and interviewed several members of the senior staff by the end of January. They anticipate releasing a report at the conclusion of the audit, tentatively scheduled for July.

Request for Proposals

CPRIT will issue a competitive request for proposal (RFP) for grant management support services in early February to continue these activities in FY 2022 and beyond. CPRIT exercised our last renewal of the current grant management support services contract with GDIT to cover fiscal year 2021, with the contract ending August 31. In accordance with state law, CPRIT received approval from state's Contract Advisory Team (CAT) prior to publishing the RFP solicitation publicly. The CAT reviews RFP documents for risk mitigation when the expected contract will exceed \$5 million.

Grant Expenses Related to COVID-19

During the month of December, CPRIT paid four FSRs for the March-May 2020 reporting period processed by the grant accounting and compliance staff. Of the four grants, three grants from two grant organizations reported COVID-related expenses totaling \$3,799, with approximately \$3,528 claimed for personnel/fringe expenses for employees who could not work or worked at reduced effort and the remainder for cancelled travel expenses. No grant FSRs processed in December for the June-August 2020 quarterly reporting period claimed any COVID-related expenses.

The decreasing number of COVID-related expense claims reflects that CPRIT has processed the majority of FSRs for March-May 2020 reporting period and that grantees have adjusted operations for the new normal.

To date, CPRIT has processed and reimbursed \$3,340,970 in total COVID-related expenses reported on 440 grant FSRs.

Communications Update

Media Highlights

- An *Austin American Statesman* article reported on Senator Jose Menéndez's proposed legislation establishing an agency to provide grants for research into emerging infectious diseases and development of vaccines. Senator Menéndez referred to CPRIT as the model for

the new agency and program. The article also ran in the *Corpus Christi Caller Times*, and the *Amarillo Globe-News* wrote an editorial piece endorsing the idea.

- Various television news coverage reported on Texas Tech University System grantees during January. KVIA in El Paso featured the HPV vaccination program “Tiempo de Vacunarte” at Texas Tech University Health Sciences Center at El Paso as part of Cervical Cancer Awareness Month. All local Amarillo networks covered the new core facility grant at the Texas Tech University Health Sciences Center in Amarillo.
- *Houston Innovation Map* featured Allterum Therapeutics for the funding the company received from CPRIT and Fannin Innovation Studio

1/13/21 – “Texas lawmaker proposes \$3 billion plan to fight future pandemics”- *Austin American Statesman* <https://www.statesman.com/story/business/2021/01/13/3-billion-proposed-texas-based-research-stop-future-pandemics/6579500002/>

1/15/21 – “TTUHSC El Paso program provides no-cost HPV vaccines to some Borderland residents” – KVIA ABC 7 El Paso <https://www.youtube.com/watch?v=NsdhaOdIQ-w&feature=youtu.be>

1/19/21 – “New imaging equipment aids TTUHSC’s cancer research”- KAMR NBC 4/KCIT Fox 14 (Nexstar) Amarillo <https://www.myhighplains.com/news/local-news/new-imaging-equipment-aids-ttuhs-cancer-research/>

1/21/21 – “Houston biotech startup raises millions to battle pediatric cancer”- *Innovation Map* <https://houston.innovationmap.com/allterum-fannin-innovation-studio-cpr-it-funding-2650054686.html>

1/24/21 – “Our view: State must be better prepared for next pandemic” – *Amarillo Globe-News* <https://www.amarillo.com/story/opinion/2021/01/24/texas-must-better-prepared-next-pandemic/6676132002/>

Social Media

January was Cervical Cancer Awareness Month. CPRIT produced a video, viewable on our YouTube page <https://www.youtube.com/watch?v=2HG4d3IOLwg> and shared on social media, featuring CPRIT grantee Dr. Abbey Berenson of The University of Texas Medical Branch at Galveston discussing cervical cancer and HPV prevention. We included this video in CPRIT’s Fiscal Year 2020 Annual Report.

Social Media Statistics

- Twitter (December 29 – January 25)

Total Tweets: 9

Tweet Impressions: 15,500

Profile Visits: 621
Mentions: 11
New Followers: 41 (2,736 total)

Top tweet: CPRIT grantee [@kmschmeler](#) of [@MDAndersonNews](#) has expanded [#CervicalCancer](#) prevention services to medically underserved populations in areas like the Rio Grande Valley. Hear from her at the 1:00 mark in this video on how CPRIT is supporting her work: [https://www.youtube.com/watch?v=AYG_xDpGQCs ...](https://www.youtube.com/watch?v=AYG_xDpGQCs...)

Impressions: 5,625
Engagements: 36

Top mention: Exited to announce new positions for two postdoctoral fellows: 1) bioinformatics 2) experimental biologist, supported by BCM, NIH, CPRIT [@CPRITTexas](#) [@bcmhouston](#) Visit hongjielilab.org Please help spread the words. Visit hongjielilab.org pic.twitter.com/QyDjwc1m2o

Engagements: 378

- LinkedIn (December 25 – January 24)

Total Updates: 8
Post Impressions: 2,300
Reactions: 57
Shares: 2
Page views: 98
Unique Visitors: 42
New followers: 12 (1107 total)

Top Update: CPRIT announces the release of five RFAs for the Academic Research program. Complete RFAs and instructions detailing applicable deadlines and requirements are available on the Apply for Funding page of CPRIT's website: <http://cprit.us/2Wn7m1y>

Impressions: 538
Clicks: 18
Reactions: 13
Engagement rate: 7.6 %

- Facebook (December 28 – January 24)

Reach: 346 people
Engagement: 297 reactions/clicks
Page Views: 105

Top Post: Check out this feature from [KVIA ABC-7](#) on [Tiempo de Vacunarte](#), a CPRIT-supported [Texas Tech University Health Sciences Center El Paso #HPV](#) vaccination program active in the border counties of El Paso, Hudspeth, Culberson, Presidio and Brewster. <https://cprit.us/2M9m11i> [#cervicalcancerawarenessmonth](#)

Post Reach: 143 people
Engagement: 5 clicks, 227 reactions, 6 shares

Upcoming Subcommittee Meetings

Listed below are the subcommittee meetings in advance of the February 17, 2021, Oversight Committee meeting.

Board Governance	February 4 at 10:00 a.m.
Audit	February 8 at 10:00 a.m.
Prevention	February 9 at 10:00 a.m.
Academic Research	February 10 at 10:00 a.m.
Product Development	February 11 at 10:00 a.m.
Nominations	February 12 at 10:30 a.m.

We will send instructions for signing onto the Zoom platform along with the subcommittee agenda and meeting materials one week prior to the meeting date. Please plan to join the subcommittee meeting a few minutes early so we can address any technology issues before the meeting start time.

CPRIT has awarded **1,584** grants totaling **\$2.661 billion**

- 244 prevention awards totaling \$277.7 million
- 1,340 academic research and product development research awards totaling \$2.383 billion

Of the \$2.383 billion in academic research and product development research awards,

- 30.6% of the funding (\$730.0 million) supports clinical research projects
- 24.6% of the funding (\$586.0 million) supports translational research projects
- 28.5% of funding (\$679.6 million) supports recruitment awards
- 13.8% of the funding (\$327.7 million) supports discovery stage research projects
- 2.5% of funding (\$60.0 million) supports training programs.

CPRIT has 12 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 5 Academic Research
- 4 Prevention



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT: COMPLIANCE PROGRAM UPDATE
DATE: FEBRUARY 8, 2021

The Chief Compliance Officer is responsible for apprising the Oversight Committee and the Chief Executive Officer of institutional compliance functions and activities, and assuring the Oversight Committee that controls are in place to prevent, detect and mitigate compliance risk. The required reporting includes quarterly updates to the Oversight Committee on CPRIT's compliance with applicable laws, rules, and agency policies. In addition, the Compliance Officer is responsible for monitoring the timely submission status of required grant recipient reports and notifying the Oversight Committee and General Counsel of a grant recipient's failure to meaningfully comply with reporting deadlines.

Submission Status of Required Grant Recipient Reports

CPRIT has \$1.4 billion in active grants under management, with 560+ grants that are either active or wrapping up grant activities. We receive an average of 560 grantee reports each month. As of January 25, 11 entities had not filed 15 Academic Research reports, seven Product Development research reports, and one Prevention report. CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

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Compliance specialists performed four desk-based financial monitoring reviews for January. Desk reviews verify that grantees expend funds in compliance with specific grant requirements and guidelines and may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission.

Onsite Reviews

CPRIT completed four virtual onsite reviews in January. Onsite reviews examine the grantee's financial and administrative operations, subcontract monitoring, inventory procedures, procurement and contracting procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance. Compliance specialists are working with one grantee to remediate onsite review findings.

Match Expenditures Review

Academic research and product development research grantees are required to demonstrate that they have available, unspent funds equal to at least one-half of the CPRIT grant award to be spent on the CPRIT-funded project. This obligation, which is often referred to as "CPRIT's matching funds requirement," requires the grantee to first certify that it has matching funds to be spent on the project, and then at the end of the grant year, to verify that the promised matching funds were actually spent. Texas Administrative Code §703.11 and CPRIT's rules allow an institution of higher education to use its federal indirect cost rate (FICR) as a credit toward the required 50% match.

Grantees are required to provide a detailed match expenditure report including date paid, vendor, description, budget category, and the amount. Compliance staff reviews grantee match expenditures for appropriateness and allowability and work with CPRIT's grant accountants and the grantee to address any deficiencies. Compliance staff performed annual match expenditures reviews for three grantees during the month of January.

Annual Compliance Attestation

CPRIT requires grantees to submit an annual Attestation Form, demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, grant contract

terms, and the Uniform Grant Management Standards. This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows compliance specialists to proactively work with grantees towards full compliance prior to a desk review or onsite review. All grantees have submitted the required annual Compliance Attestation form. Compliance staff is working with two grantees to remediate areas identified as non-compliant.

Training and Support

CPRIT staff conducted one new grantee training webinar in January for Invectys USA. The training covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, CPRIT requires new grantees to complete the initial compliance training program prior to receiving disbursement of grant award funds.

Annual compliance training webinars have been scheduled for March 9-11. Trainings are specific to each program area (Academic Research, Product Development Research, and Prevention) and allow for an interactive experience and opportunity to focus on topics relevant to each program. The trainings cover grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. This is the first training series offered this year in support of the annual compliance training mandate that requires the Authorized Signing Official (ASO) and at least one other employee from each grantee organization to attend an annual compliance training by December 31 of each year.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE
FROM: JAMES WILLSON, M.D., CPRIT CHIEF SCIENTIFIC OFFICER
SUBJECT: ACADEMIC RESEARCH PROGRAM UPDATES
DATE: FEBRUARY 17, 2021

FY2021 Cycle 1 (21.1)

Table 1 displays an overview of applications submitted by October 28, 2020 for the FY2021 Cycle 1, Research Training Awards RFA. Peer review will be conducted virtually on February 18, 2021. Dr. Willson will present the Scientific Review Council’s recommendations to PIC and the Oversight Committee in May 2021.

Table 1: FY2021.1 Submission Data

RFA Mechanism	# Applications Submitted	Requested Funding
Research Training Awards	15	\$57,385,186

FY2021 Cycle 2 (21.2)

Table 2 displays an overview of applications submitted by mechanism on January 27, 2021 for FY2021 Cycle 2 RFAs. Dr. Willson will present the Scientific Review Council’s recommendations to PIC and the Oversight Committee in August 2021.

Table 2: FY2021 Cycle 2 (21.2) Submission Data

RFA Mechanism	# Applications Submitted	Requested Funding
Core Facility Support Awards	25	\$95,848,572
Clinical Trials Network Awards	5	\$13,481,740
Early Clinical Investigator Award	11	\$16,426,401
High-Impact/High Risk Awards	107	\$26,501,441
Texas Clinical Trials Participation Program Award	4	\$5,982,538
Texas Regional Excellence in Cancer Award	7	\$41,786,641
Total	159	\$200,027,333

FY22.1 RFA Mechanisms

- **Individual Investigator Research Awards (IIRA)**
Supports applications for innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. Areas of interest include laboratory research, translational studies, and/or clinical investigations. Competitive renewal applications accepted.
Award: Up to \$350,000 per year. Exceptions permitted if extremely well justified; maximum duration: 3 years.
- **Individual Investigator Research Awards for Computational Systems Biology of Cancer (IIRACSBC)**
Supports applications for innovative mathematical and/or computational research projects addressing questions that will advance current knowledge in the (a) mechanisms that tie altered gene expression and downstream molecular mechanisms to functional cancer phenotypes and/or (b) mechanisms that tie tumor morphology to functional cancer phenotypes and/or mechanisms that tie treatment sequence and combination to evolving functional cancer phenotypes (that emerge as a result of treatment selection).
Award: Up to \$400,000 in total costs per year for up to 4 years. Exceptions permitted if extremely well justified.
- **Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA)**
Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, progression, detection, or treatment of cancer in children and adolescents. Laboratory, clinical, or population-based studies are all acceptable. CPRIT expects the outcome of the research to reduce the incidence, morbidity, or mortality from cancer in children and/or adolescents in the near or long term. Competitive renewal applications accepted.
Award: Up to \$350,000 per year. Applicants that plan on conducting a clinical trial as part of the project may request up to \$500,000 in total costs. Exceptions permitted if extremely well justified; maximum duration: 4 years.

- **Individual Investigator Research Awards for Prevention and Early Detection (IIRAP)**

Supports applications which propose clinical and population-based projects designed to develop effective prevention and early detection interventions to reduce cancer risk, mortality, and morbidity among Texans. Projects that propose such research collaborations with existing CPRIT Prevention Program awardees including the CPRIT funded *Texas Collaborative Center for Hepatocellular Cancer*

(<https://www.bcm.edu/research/labs-and-centers/research-centers/texas-collaborative-center-for-hepatocellular-cancer>) are strongly encouraged.

Award: Up to \$500,000 per year. Exceptions permitted if extremely well justified; maximum duration: 4 years.

- **Individual Investigator Research Awards for Clinical Translation (IIRACT)**

Supports applications that propose innovative cancer clinical studies that are hypothesis driven and involve patients enrolled prospectively on a clinical trial. Areas of interest include clinical studies of new or repurposed drugs, hormonal therapies, immune therapies, surgery, radiation therapy, stem cell transplantation, combinations of interventions, or therapeutic devices.

Award: Up to \$500,000 per year. Maximum duration: 4 years. Exceptions permitted if extremely well justified.

FY22.1 RFA Timelines	
Post RFAs to CPRITs Application Receipt System (CARS)	January 13, 2021
Open CARS (application receipt begins)	March 3, 2021
Close CARS (application receipt ends)	June 2, 2021
Peer Review	October 2021
Program Integration Committee	February 2022
Oversight Committee	February 2022



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: RAMONA MAGID, CHIEF PREVENTION OFFICER
SUBJECT: PREVENTION PROGRAM UPDATE
DATE: FEBRUARY 17, 2021

FY 2021 Cycle 1 (20.1) Prevention Applications

CPRIT released one RFA in August for the first grant cycle of FY 2020. Twelve applications were received by the October 5 deadline. The twelve applications requesting \$26,133,587 underwent peer review on January 19, 2021. The Prevention Review Council will meet on March 4 to review the results of the peer review panel. Ms. Magid will present the PRC recommendations to the PIC and to the Oversight Committee in May 2021.

Mechanism	Number Received	Total \$ Requested
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	12	\$26,133,587

FY 2021 Cycle 2 (20.2) Prevention RFAs

CPRIT released four (4) RFAs on October 15 for the second cycle of FY 2021. The application deadline was February 10, 2021. Peer review is scheduled for April 2021. Ms. Magid will present the PRC’s recommendations to the PIC and the Oversight Committee in August 2021.

Impact of COVID

The Prevention subcommittee met on February 9. The members requested an update on the impact COVID is having on screenings, diagnostics and vaccinations provided by CPRIT grantees. From March 2019 – February 2020, the average number of clinical services was 78,500 per quarter. The months of March through November 2020 during the COVID pandemic showed a 44% decrease, a total of 43,700 clinical services.

Proposed FY2022 RFA Descriptions and Timeline

Dissemination of CPRIT-Funded Cancer Control Interventions

This award mechanism seeks to fund projects that will facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based cancer prevention and control interventions across Texas. The proposed project should be able to develop one or more "products" based on the results of the CPRIT-funded intervention. The proposed project should also identify and assist others to prepare to implement the intervention and/or prepare for grant funding.

Award: Maximum of \$300,000; Maximum duration of 24 months.

Evidence-Based Cancer Prevention Services

Evidence-Based Cancer Prevention Services - This award mechanism seeks to fund projects that will deliver evidence-based cancer prevention and control clinical services. Priority will be given to projects that propose to address CPRIT areas of emphasis and serve areas of the state not well addressed by current CPRIT funded projects.

Award: Maximum of \$1M; Maximum duration of 36 months.

Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

This award mechanism seeks to support the coordination and expansion of evidence-based services to prevent cancer in underserved populations who do not have adequate access to cancer prevention interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community and use evidence-based models shown to work in similar communities to prevent and control these cancers. Currently funded CPRIT projects should propose to expand their programs to include additional types of prevention clinical services and/or an expansion of current clinical services into additional counties. For projects requesting a maintenance expansion, expansion of clinical services or geographic area is optional; however, the number of clinical services delivered should be substantially increased.

Initial Expansion Award: Maximum of \$2M; Maximum duration of 36 months.

Maintenance Expansion Award: Maximum of \$2.5M; Maximum duration of 60 months.

Tobacco Control and Lung Cancer Screening

This award mechanism seeks to fund programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs across the state, thereby providing greater access for underserved populations and reducing the incidence and mortality rates of tobacco-related cancers. This RFA seeks to promote and deliver evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth.

Award: Maximum of \$1M for new projects and \$2M for expansion projects; Maximum duration of 36 months.

Prevention Program Assessment

This award mechanism solicits applications for one project to assess the initial progress of the CPRIT Prevention Program since 2010 and to develop an assessment plan for the next stage of the CPRIT Prevention Program. The evaluation will use a mixed-methods approach, which combines quantitative and qualitative data to provide evidence of effectiveness and information about how CPRIT-related changes are embedded and sustained in organizations and populations. Evaluation findings will be used to improve program effectiveness and to inform decisions about future program development.

Award: Maximum of \$750,000; Maximum duration of 24 months.

Other Activities

Ms. Magid has been asked to serve on the Stakeholder and Community Advisory Council for the CDC CRCCP grant received by The University of Texas Health Science Center at Houston in partnership with UT MD Anderson Center and The University of Texas Health Science Center Tyler. This council will work together to collaborate to identify and reduce barriers to the implementation of evidence-based interventions to increase colorectal cancer screening rates across various clinical sites in Texas.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: CINDY WALKERPEACH, PHD
CHIEF PRODUCT DEVELOPMENT OFFICER
SUBJECT: PRODUCT DEVELOPMENT RESEARCH UPDATE
DATE: 08 FEBRUARY 2021

Product Development Research Award Update

Product Development Research FY2021 Cycle 1

CPRIT released the TXCO, RELCO and SEED Product Development Research RFAs on November 9, 2020, and accepted applications through January 27, 2021. Applicants submitted thirty-six (36) responses to the open RFAs, which are currently undergoing administrative review. See Table 1. The peer review screen is planned for March 22-23, 2021, with selected applicants invited to in-person presentations (via Zoom) from April 19-22, 2021. The Chief Product Development Officer anticipates presenting the peer review recommendations for FY2021 Cycle 1 to the Oversight Committee during the August 2021 Oversight Committee meeting.

Table 1: Product Development Research FY2021 Cycle 1 Application Data by Mechanism

Mechanism	Applications Received	Funds Requested (millions)
Texas Company	8	\$99,869,430
Relocation Company	6	\$97,956,112
Seed Company	22	\$56,471,137
TOTAL	36	\$254,296,679

FY2022 Proposed Product Development Research RFAs

With the Oversight Committee’s approval, Product Development Research (PDR) proposes to release the standard TXCO, RELCO and SEED RFAs in FY2022 as were offered in FY2021 and, as reference, are described below. In FY2022, PDR plans to return to the standard number of application cycles, two (2), offered per fiscal year. The Chief Product Development Officer

anticipates presenting the FY2022 Cycle 1 and FY2022 Cycle 2 award recommendations during the Oversight Committee meetings in February 2022 and August 2022, respectively.

- *Texas Company Product Development Research Award (TEXCO)*

This award mechanism seeks to support early stage “startup” and established companies in the development of innovative products and services with significant potential impact on cancer patient care. The proposed project must further the development of new products or services for the diagnosis, treatment, or prevention of cancer; must foster a robust biotechnology industry ecosystem; or must fulfill a critical unmet need in cancer patient care. Companies must be headquartered in Texas.

Strong candidates for the TXCO award have developed a sufficiently robust data package, value proposition, regulatory strategy, manufacturing plan, and experienced business/management team to warrant the amount of funding requested.

Award: Maximum amount \$20 million over 36 months

- *Relocation Company Product Development Research Award (RELCO)*

This award mechanism seeks to support early stage “startup” and established companies in the development of innovative products and services with significant potential impact on cancer patient care. The proposed project must further the development of new products or services for the diagnosis, treatment, or prevention of cancer; must foster a robust biotechnology industry ecosystem; or must fulfill a critical unmet need in cancer patient care. Companies must relocate to Texas upon receipt of award.

Strong candidates for the RELCO award have developed a sufficiently robust data package, value proposition, regulatory strategy, manufacturing plan, and experienced business/management team to warrant the amount of funding requested.

Award: Maximum amount \$20 million over 36 months

- *Seed Award for Product Development Research (SEED)*

This award mechanism seeks to support early stage “startup” companies in the development of innovative products and services with significant potential impact on cancer patient care.

The proposed project must further the development of new products or services for the diagnosis, treatment, or prevention of cancer; must foster a robust biotechnology industry ecosystem; or must fulfill a critical unmet need in cancer patient care. Company applicants must be headquartered in Texas or be willing to relocate to Texas upon receipt of award

Strong candidates for the SEED award have developed compelling discovery stage data and/or developed a working prototype (if applicable) around a novel compound, diagnostic, device, computational tool, etc. that warrants further development efforts to establish proof of concept (POC) on the early pathway to commercial product. In addition, strong candidates have at a minimum developed a strong value proposition, preliminary regulatory strategy,

preliminary manufacturing plan, and early business/management team to warrant the amount of funding requested.

Award: Maximum amount of \$3 million over 36 months.

**February 2021 Oversight Committee
Internal Audit Status Report
As of January 31, 2021**

Weaver and Tidwell, LLP (Weaver) is the outsourced internal auditor of the Cancer Prevention Research Institute of Texas (CPRIT). The Weaver engagement team is led by Daniel Graves, Partner and Alyssa Martin, Partner.

2021 Internal Audit Plan and Schedule

Based on the approved 2021 Internal Audit Plan by the Oversight Committee, we have coordinated and planned the timing of the internal audits and follow-up procedures for the 2021 Internal Audit Plan.

2021 INTERNAL AUDITS		
Internal Audit	Description	Status
Sunset Self-Assessment Advisory Audit	Internal Audit will compare the results of the latest Internal Audit Risk Assessment with the reporting requirements in the Sunset Commission Self-Assessment Report (SAR) to provide an overlay of a risk-based framework to complete the SAR, as well as providing mapping of historical internal audit results, and corresponding agency improvements, to each section of the report. Additionally internal audit will evaluate the processes used to compile the information included in the SAR and will validate the accuracy of key data to be included in the report, defined in Texas Government Code 325.011. Internal Audit will also verify that CPRIT has the required policies and procedures in place, in preparation for the Sunset Advisory Commission Review.	In Planning
Information Technology General Computer Controls	Internal Audit will evaluate the risks and internal controls in place related to CPRIT's Information Technology practices. Activities to be evaluated will include Network Operations, Help Desk Support, Change Management, Website Maintenance, Back-Up and Recovery.	February –March 2021
Records Management – Grantee Compliance Records Advisory Audit	Internal Audit will provide audit advisory services to evaluate the planning process for the grantee compliance record migration from a third-party designed system to the integrated CPRIT system. Evaluation of the designed process will include the validation of the system architecture design and data mapping of the file migration plan. Consulting services will also include the validation of the system configuration upon implementation, verification of the completeness of the data migration and testing the accuracy of data classification and mapping.	May 2021

2021 INTERNAL AUDIT FOLLOW-UPS		
Information Security Follow-Up	Internal Audit will perform follow-up procedures on the open findings from the 2016 Internal Audit to ensure corrective action has been taken.	February - March With the IT General Controls Audit
Communications Follow-Up • 1 High Finding • 2 Moderate Findings	Internal Audit will perform follow-up procedures on the 3 open findings from the 2018 Internal Audit to ensure corrective action has been taken.	May 2021
Governance Follow-up • 1 Moderate Finding	Internal Audit will perform follow-up procedures on the open finding from the 2020 Internal Audit to ensure corrective action has been taken.	May 2021
Disaster Recovery and Business Continuity Planning Advisory Follow-up	Internal Audit will perform follow-up procedures on the recommendations provided from the 2020 Advisory project to evaluate the corrective action and provide additional recommendations.	June 2021

We have prepared a summary schedule of audits, their status and a summary of the findings by risk rating. The schedule maps out the internal audit and follow-up procedures performed, by year, the report date, report rating, and the findings by risk rating. The summary schedule is attached.

In addition, we have participated in the State Auditor's Office (SAO) audit of CPRIT Grants. Through the SAO's planning process, we have reviewed the internal audits over the grant management cycle with the SAO's auditors. We have also participated in their fraud assessment interviews.



Daniel Graves, CPA, Internal Auditor
Partner
Weaver and Tidwell L.L.P.



Alyssa G. Martin, CPA, MBA, Internal Auditor
Partner
Weaver and Tidwell L.L.P.

Cancer Prevention and Research Institute of Texas
 Schedule of Audits, Status, and Findings Summary
 As of January 31, 2021

Audit	Fiscal Year	Status/Timing	Report Date	Report Rating	Open Findings				Closed Findings				Total Findings			
					High	Mod	Low	Total	High	Mod	Low	Total	High	Mod	Low	Total
Fiscal Year 2015																
Grant Management	2015	Complete	July 27, 2015	Satisfactory	-	8	1	9	-	-	-	-	-	8	1	9
Expenditures Internal Audit	2015	Complete	August 24, 2015	Strong	-	-	2	2	-	-	-	-	-	-	2	2
2014 Governance and IT Follow-Up	2015	Complete	August 14, 2015	Satisfactory	-	-	-	9	-	-	-	7	-	1	1	2
2014 Grantee Monitoring Follow-Up	2015	Complete	July 31, 2015	Satisfactory	-	-	-	14	-	-	-	11	1	-	2	3
Fiscal Year 2015 Subtotal					-	8	3	34	-	-	-	18	1	9	6	16
Fiscal Year 2016																
Commodity and Service Contracts Internal Audit	2016	Complete	May 13, 2016	Satisfactory	-	3	2	5	-	-	-	-	-	3	2	5
Revenue Internal Audit	2016	Complete	July 8, 2016	Strong	-	-	2	2	-	-	-	-	-	-	2	2
Information Security Internal Audit	2016	Complete	August 3, 2016													
Cash Management Internal Audit	2016	Complete	August 12, 2016	Strong	-	1	-	1	-	-	-	-	-	1	-	1
2015 Grant Management Follow-Up	2016	Complete	June 9, 2016	Strong	-	8	1	9	-	8	1	9	-	-	-	-
2015 Information Technology Follow-Up	2016	Complete	N/A	N/A	-	1	1	2	-	1	1	2	-	-	-	-
Fiscal Year 2016 Subtotal					-	13	6	19	-	9	2	11	-	4	4	8
Fiscal Year 2017																
Training Program Internal Audit	2017	Complete	March 10, 2017	Strong	-	2	-	2	-	-	-	-	-	2	-	2
Internal Agency Compliance	2017	Complete	April 17, 2017	Strong	-	1	-	1	-	-	-	-	-	1	-	1
Pre-Award Grant Management	2017	Complete	May 30, 2017	Satisfactory	1	2	-	3	-	-	-	-	1	2	-	3
Procurement and P-Card Internal Audit	2017	Complete	August 4, 2017	Satisfactory	-	7	2	9	-	-	-	-	-	7	2	9
2016 Information Security Follow-Up	2017	Complete	May 30, 2017													
2016 Commodity and Service Contracts Follow-Up	2017	Complete	July 13, 2017	Strong	-	3	2	5	-	3	2	5	-	-	-	-
2016 Revenue Follow-Up	2017	Complete	July 8, 2017	Strong	-	-	2	2	-	-	2	2	-	-	-	-
2016 Cash Management Follow-Up	2017	Complete	July 13, 2017	Strong	-	1	-	1	-	1	-	1	-	-	-	-
Fiscal Year 2017 Subtotal					1	16	6	23	-	4	4	8	1	12	2	15
Fiscal Year 2018																
Post Award Grant Monitoring Internal Audit	2018	Complete	February 1, 2018	Strong	-	1	-	1	-	-	-	-	-	1	-	1
Grant Contracting Internal Audit	2018	Complete	April 30, 2018	Satisfactory	1	4	-	5	-	-	-	-	1	4	-	5
Communications Internal Audit	2018	Complete	July 17, 2018													
2016 Information Security Follow-Up	2018	Complete	January 19, 2018	Strong	-	2	-	2	-	2	-	2	-	-	-	-
2017 Training Program Follow-Up	2018	Complete	January 19, 2018	Strong	-	1	-	1	-	1	-	1	-	-	-	-
2017 Internal Agency Compliance Follow-Up	2018	Complete	April 24, 2018	Strong	1	2	-	3	1	2	-	3	-	-	-	-
2017 Pre-Award Grant Management Follow-Up	2018	Complete	April 30, 2018	Strong	-	7	2	9	-	6	2	8	-	1	-	1
2017 Procurement and P-Card Follow-Up	2018	Complete	April 30, 2018	Strong	-	7	2	9	-	6	2	8	-	1	-	1
Fiscal Year 2018 Subtotal					2	17	2	21	1	11	2	14	1	6	-	7
Fiscal Year 2019																
State Reporting Internal Audit	2019	Complete	January 16, 2019	Strong	-	-	2	2	-	-	2	2	-	-	-	-
Budget and Planning	2019	Complete	January 16, 2019	Strong	-	-	-	-	-	-	-	-	-	-	-	-
2017 SAO Performance Measures Follow-up	2019	Complete	December 6, 2018	Strong	-	-	3	3	-	-	3	3	-	-	-	-
2016 Information Security Follow-Up	2019	Cancelled	N/A													
2018 Communications Follow-Up	2019	Complete	August 30, 2019	Satisfactory	1	4	-	5	-	2	-	2	1	2	-	3
2018 Post Award Grant Monitoring Follow-Up	2019	Complete	April 11, 2019	Strong	-	1	-	1	-	1	-	1	-	-	-	-
2018 Grant Contracting Follow-Up	2019	Complete	August 1, 2019	Strong	-	7	2	9	-	7	2	9	-	-	-	-
2017 Procurement and P-Card Follow-Up	2019	Complete	August 1, 2019	Strong	-	7	2	9	-	7	2	9	-	-	-	-
Fiscal Year 2019 Subtotal					1	12	7	20	-	10	7	17	1	2	-	3
Fiscal Year 2020																
Governance	2020	Complete	October 30, 2020	Strong	-	1	-	1	-	-	-	-	-	1	-	1
Disaster Recovery and Business Continuity Planning	2020	Complete	October 28, 2020	N/A	-	-	-	-	-	-	-	-	-	-	-	-
2016 Information Security Follow-Up	2020	August 2020	N/A													
2018 Communications Follow-Up	2020	November 2020	N/A	N/A	1	4	-	5	-	2	-	2	1	2	-	3
2019 State Reporting Follow-Up	2020	July 2020	July 20, 2020	Strong	-	-	2	2	-	-	2	2	-	-	-	-
Fiscal Year 2020 Subtotal					1	5	2	8	-	2	2	4	1	3	-	4

8-3

FISCAL YEAR 2020 SUMMARY																	
Audit	Fiscal Year	Status/Timing	Report Date	Report Rating	Findings				Closed Findings				Total Open Findings				Timing of Follow-Up Procedures by IA
					High	Mod	Low	Total	High	Mod	Low	Total	High	Mod	Low	Total	
Governance	2020	July 2020	October 30, 2020	Strong	-	1	-	1	-	-	-	-	-	1	-	1	May 2021
Disaster Recovery and Business Continuity Planning	2020	July-August 2020	October 28, 2020	N/A	-	-	-	-	-	-	-	-	-	-	-	-	June 2021
2016 Information Security Follow-Up	2020	August 2020	N/A														February 2021
2018 Communications Follow-Up	2020	November 2020	N/A	N/A	1	4	-	5	-	2	-	2	1	2	-	3	May 2021
Total Findings For Internal Audit Follow-Up					1	5	-	6	-	2	-	2	1	3	-	4	



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: CAMERON ECKEL, ASSISTANT GENERAL COUNSEL
SUBJECT: APPOINTMENT TO THE SCIENTIFIC RESEARCH AND PREVENTION PROGRAMS COMMITTEE
DATE: FEBRUARY 5, 2021

Summary and Recommendation

The Chief Executive Officer has appointed three experts to CPRIT's Scientific Research and Prevention Programs Committee. CPRIT's statute requires Oversight Committee approval for the appointments. The Nominations Subcommittee will discuss the appointments at its meeting on February 12.

Discussion

Scientific Research and Prevention Programs committee members (also referred to as "peer reviewers") are responsible for reviewing grant applications and recommending grant awards for meritorious projects addressing cancer prevention and research, including product development research. Peer reviewers perform a significant role for the state; all CPRIT grant awards must first be recommended by a Scientific Research and Prevention Programs committee. Individuals appointed to serve as CPRIT's Scientific Research and Prevention Programs committee members must be exceptionally qualified, highly respected, well-established members of the cancer research, product development research, and prevention communities.

Texas Health and Safety Code Section 102.151(a) directs the Chief Executive Officer to appoint members to the Scientific Research and Prevention Programs committees. The CEO's appointments are final once approved by a simple majority of the Oversight Committee. The Nominations Subcommittee charter assigns the subcommittee with the responsibility "to circulate to Oversight Committee members in advance of a public meeting written notification of the committee's intent to make the nomination, along with such information about the nominee as may be relevant."

The nominations subcommittee will review the peer reviewer appointments at its February 12 meeting.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Scientific Research and Prevention Programs Committee (SRPP) Appointments

Appointee	SRPP Assignment	Organization
Academic Research		
Martin Pomper, M.D., Ph.D.	Scientific Review Council (SRC) member; Chair of Imaging Technology and Informatics review panel	Henry N. Wagner Professor of Radiology; Director, Division of Nuclear Medicine and Molecular Imaging; Associate Dean for Entrepreneurship and Technology Development, Johns Hopkins
Trey Ideker, Ph.D.	SRC Ad Hoc reviewer	Professor, Division of Genetics Co-Director, Graduate Program in Bioinformatics UC San Diego, CA
Product Development Research		
Joya Delgado Harris, MPH	Advocate reviewer	Director, Research Integration, American Cancer Society

BIOGRAPHICAL SKETCH

NAME: Pomper, Martin Gilbert

eRA COMMONS USER NAME: mpomper1

POSITION TITLE: Henry N. Wagner Professor of Radiology; Director, Division of Nuclear Medicine and Molecular Imaging; Associate Dean for Entrepreneurship and Technology Development

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
University of Illinois at Urbana-Champaign	B.S.	05/1982	Biochemistry
University of Illinois at Urbana-Champaign	Ph.D.	12/1989	Chemistry (organic)
University of Illinois at Urbana-Champaign	M.D.	05/1990	Medicine

A. Personal Statement

For the past 20+ years our group has been dedicated to the development and application of new imaging agents, with a focus on cancer. We currently consist of ~40 individuals, including graduate students, technicians, postdoctoral fellows, junior faculty, rotating students, residents, research coordinators and clinicians. Most of our work involves chemical and radiochemical synthesis, but we have several projects involving molecular-genetic imaging as well as nanotechnology and target discovery/validation, and we adapt and generate our own biological assays and translate quantitative imaging techniques to the clinic. In addition to being a clinical division director, I lead other imaging-based initiatives at the university, including two cGMP facilities, the PET Center and the Center for Translational Molecular Imaging. We have an incipient informatics/AI program to support workflow and interpretation of imaging and theranostic agents we develop. We are involved in several commercial enterprises and agreements to enhance translation of our work. In the context of this proposal I will oversee chemical and some biological aspects of Aims 1 and 2 and radiochemical and medical aspects of Aim 3.

1. Minn I, Huss DJ, Ahn HH, Chinn TM, Park A, Jones J, Brummet M, Rowe SP, Sysa-Shah P, Du Y, Levitsky HI, Pomper MG. Imaging CAR T therapy with PSMA-targeted positron emission tomography. *Sci Adv* 2019; 5: PMID: PMC6609218.
2. Banerjee SR, Kumar V, Lisok A, Chen J, Minn I, Brummet M, Boinapally S, Cole M, Ngen E, Wharram B, Brayton C, Hobbs RF, Pomper MG. ¹⁷⁷Lu-labeled low-molecular-weight agents for PSMA-targeted radiopharmaceutical therapy. *Eur J Nucl Med Mol Imaging* 2019; 46:2545-2557.
3. Park JS, Oh y, Park YJ, Park O, Yang H, Slania S, Hummers LK, Shah AA, An HT, Jang J, Horton MR, Shin J, Dietz HC, Song E, Na DH, Park EJ, Kim K, Lee KC, Roschke VV, Hanes J, Pomper MG, Lee S. Targeting of dermal myofibroblasts through death receptor 5 arrests fibrosis in mouse models of scleroderma. *Nat Commun* 2019; 10:1128. PMID: PMC6408468.
4. Horti AG, Naik R, Foss CA, Minn I, Misheneva V, Du Y, Wang Y, Mathews WB, Wu Y, Hall A, LaCourse C, Ahn HH, Nam H, Lesniak WG, Valentine H, Pletnikova O, Troncoso JC, Smith MD, Calabresi PA, Savonenko AV, Dannals RF, Pletnikov MV, Pomper MG. PET imaging of microglia by targeting macrophage colony-stimulating factor 1 receptor (CSF1R). *Proc Natl Acad Sci USA* 2019; 116:1686-1691. PMID: PMC6358677.

B. Positions and Honors**Positions and Employment**

1990—1991	Intern in Medicine, Johns Hopkins Hospital, Baltimore, MD (Osler Service)
1991—1995	Resident in Radiology, Johns Hopkins Hospital, Baltimore, MD
1994—1995	Resident in Nuclear Medicine, Johns Hopkins Hospital, Baltimore, MD
1994—1996	Fellow in Neuroradiology, Johns Hopkins Hospital, Baltimore, MD
1996—2002	Assistant Professor, Russell H. Morgan Department of Radiology, Johns Hopkins University, Baltimore, MD

- 2002—2007 Associate Professor, Radiology, Pharmacology and Molecular Sciences, Oncology, Johns Hopkins University, Baltimore, MD; Department of Environmental Health Sciences, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD
- 2007—present Professor, Radiology, Pharmacology and Molecular Sciences, Oncology, Radiation Oncology and Molecular Radiation Sciences, Psychiatry, Pathobiology, Materials Science and Engineering, Chemical and Biomolecular Engineering, Urology, Johns Hopkins University, Baltimore, MD; Department of Environmental Health Sciences, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD.
- 2018—present Professor of Biomedical Engineering
- 2011—2016 William R. Brody Professor of Radiology (inaugural)

Other Experience and Professional Memberships

- 2000—present Associate Director, Johns Hopkins *In Vivo* Cellular and Molecular Imaging Center (ICMIC)
- 2001—2013 Director, Johns Hopkins Small Animal Imaging Resource Program (SAIRP)
- 2001—present Ad Hoc Reviewer, National Institutes of Health
- 2005—2006 Treasurer, Society for Molecular Imaging
- 2005—present Steering Committee (founding member), Johns Hopkins Institute for NanoBioTechnology
- 2006—2008 President, Society of Nuclear Medicine's Molecular Imaging Center of Excellence
- 2007—2012 Board of Scientific Counselors, NIH Clinical Center
- 2007—2012 Editor-in-Chief, *Molecular Imaging*
- 2009—2013 Member, Clinical Molecular Imaging and Probes Study Section (NIH)
- 2009—present CPRIT Scientific Review Panel (Imaging Technology and Informatics)
- 2010—2015 Co-Director, Johns Hopkins Center for Cancer Nanotechnology Excellence
- 2010—present Director, Johns Hopkins Center for Translational Molecular Imaging
- 2013—present Board of Scientific Counselors, NIBIB, Clinical Center (*ad hoc*)
- 2014—2019 Co-Founder and Member of the Board, Cancer Targeting Systems, Inc.
- 2014—present Co-Founder and Member of the Board, Theraly Pharmaceuticals, Inc.
- 2015—present Director, Johns Hopkins Division of Nuclear Medicine and Molecular Imaging
- 2016 Lancet Oncology Commission to the NCI Blue Ribbon Report (Cancer Moonshot)
- 2017—present Director, Resource for Molecular Imaging Agents in Precision Medicine
- 2018—2019 President, World Molecular Imaging Society
- 2018—present Co-Founder and CSO, Precision Molecular, Inc.

Honors

- 1982—1990 Medical Scholars Program, University of Illinois at Urbana-Champaign
- 1988 Berson-Yalow Award, Society of Nuclear Medicine (first author)
- 1988 R. C. Fuson Award for Excellence in Organic Chemistry, University of Illinois
- 1995 William Gatewood Award (Department of Radiology, Johns Hopkins Hospital)
- 1996—1998 Radiological Society of North America, Scholar's Award
- 1997—1999 NARSAD Young Investigator Award – Marcia Simon Investigator
- 2007 Berson-Yalow Award, Society of Nuclear Medicine (co-author)
- 2008 Distinguished Service Award, Society of Nuclear Medicine
- 2011 Berson-Yalow Award, Society of Nuclear Medicine (senior author)
- 2012 Distinguished Investigator of the Academy of Radiology Research
- 2014 Elected to the Interurban Clinical Club
- 2014—2015 Johns Hopkins Radiology Resident Mentoring Award
- 2014, 16, 18 Most Influential Radiology Researcher Semifinalist (AuntMinnie.com)
- 2016 Member, National Academy of Inventors (Johns Hopkins Chapter)
- 2017 Paul C. Aebersold Award, Society of Nuclear Medicine and Molecular Imaging
- 2017 Member, National Academy of Medicine (formerly the Institute of Medicine)
- 2017 America's Top Physicians (Consumer's Research Council of America)
- 2018 Excellence in Teaching Award, Department of Urology, Johns Hopkins University

C. Contributions to Science

1. *New tools for imaging and treating prostate cancer.* Prostate cancer is difficult to manage. Since the late 1990s our group has focused on developing low-molecular-weight (LMW) imaging and therapeutic agents targeting the prostate-specific membrane antigen (PSMA) for a variety of modalities. The goal is to have a convenient set of tools for imaging primary disease, provide intra-operative guidance, and enable accurate staging and therapeutic monitoring. We synthesized the first LMW PSMA-targeted imaging agent, which was for PET, as well as the first agents for SPECT and the first viable compound for optical imaging. We performed the first human PET studies with such an agent, and synthesized the first ⁶⁸Ga-based agent, the first bivalent agent and the first nanoparticle targeted to PSMA. Most of those agents have been licensed to commercial concerns and several have been translated clinically, most notably [¹⁸F]DCFPyL, for which Progenics Pharmaceuticals has recently submitted an NDA to the FDA. PSMA-targeted imaging with LMW agents is widely regarded as the method by which to image prostate cancer, supplanting bone scan, CT and other agents worldwide. Thousands of patients have been studied using an analog of our original ⁶⁸Ga-labeled agent, and molecular radiotherapeutics are being used clinically based on design rules we developed for our metal chelating PSMA-targeting agents.
 - a. Pomper MG, Musachio JL, Zhang J, Zhou Y, Scheffel U, Hilton J, Maini A, Dannals RF, Wong DF, Kozikowski AP. ¹¹C-MCG: Synthesis, uptake selectivity and primate PET of a probe for glutamate carboxypeptidase II (NAALADase). *Mol Imaging* 2002; 1:96-101.
 - b. Banerjee SR, Foss CA, Castanares M, Mease RC, Byun Y, Fox JJ, Hilton J, Lupold SE, Kozikowski AP, Pomper MG. Synthesis and evaluation of technetium-99m- and rhenium-labeled inhibitors of the prostate-specific membrane antigen. *J Med Chem* 2008; 51:4504-17. PMID: PMC3336105.
 - c. Banerjee SR, Pullambhatla M, Byun Y, Nimmagadda S, Foss CA, Green G, Fox JJ, Lupold SE, Mease RC, Pomper MG. Sequential SPECT and optical imaging of experimental models of prostate cancer with a dual modality inhibitor of the prostate-specific membrane antigen. *Angew Chem Int Ed Engl* 2011; 50:9167-70. PMID: PMC3192196.
 - d. Phillips R, Shi WY, Deek M, Radwan N, Lim SJ, Antonarakis ES, Rowe SP, Ross AE, Gorin MA, Deville C, Greco SC, Wang H, Denmeade SR, Paller CJ, Dipasquale S, DeWeese TL, Song DY, Wang H, Carducci MA, Pienta KJ, Pomper MG, Dicker AP, Eisenberger MA, Alizadeh AA, Diehn M, Tran PT. Outcomes of observation vs stereotactic ablative radiation for oligometastatic prostate cancer: The ORIOLE phase 2 randomized clinical trial. *JAMA Oncol* 2020 Mar 26. doi: 10.1001/jamaoncol.2020.0147.
2. *New tools for molecular imaging.* Since graduate school I have been interested in applying chemistry to medical imaging and therapy. While most of our agents are of low molecular weight and are radioactive, we have also developed reagents that could be leveraged in assays and to study tissues other than cancer, e.g., infection, the collagen matrix, agents for isolating cancer stem cells and agents detected by chemical exchange saturation transfer (CEST) MR imaging.
 - a. Bettgowda C, Foss CA, Wang Y, Fox J, Zhou S, Kinzler K, Vogelstein B, Pomper MG. Imaging bacterial infection in live animals with radiolabeled FIAU. *Proc Natl Acad Sci USA* 2005; 102:1145-51150. PMID: PMC54851.
 - b. Li Y, Foss CA, Summerfield DD, Doyle JJ, Torok CM, Dietz HC, Pomper MG, Yu SM. Targeting collagen strands by photo-triggered triple-helix hybridization. *Proc Natl Acad Sci U S A*. 2012; 109:14767-72. PMID: PMC3443117.
 - c. Minn I, Wang H, Mease RC, Byun Y, Yang X, Wang J, Leach SD, Pomper MG. A red-shifted fluorescent substrate for aldehyde dehydrogenase. *Nat Commun* 2014; 5:3662-3670. PMID: PMC4063304.
 - d. Liu G, Banerjee SR, Yang X, Yadav N, Lisok A, Jablonska A, Xu J, Li Y, Pomper MG, van Zijl P. Receptor imaging for MRI using a biodegradable dextran probe. *Nat Biomed Eng* 2017; 1:977-982. PMID: PMC5810963.
3. *Molecular-genetic imaging.* Imaging gene expression *in vivo* is increasingly important as new therapeutics that address genetic and epigenic abnormalities, new agents to manipulate gene expression, new non-viral gene delivery vehicles and the significance of new genes and their products are uncovered. We have taken two approaches to image gene expression *in vivo*, one leveraging existence of genes already present in cancer, which can be reactivated to produce a protein that can be imaged (gammaherpesvirus thymidine

kinase), and the other which uses a nanoparticle delivery vehicle, currently linear polyethyleneimine, to ensure clinical translation. The imaging of activated gammaherpesvirus thymidine kinase was the first demonstration of specific imaging of activated endogenous gene expression, i.e., without introduction of a transgene, and can be used eventually to treat patients with gammaherpesvirus-associated malignancies. The second method uses universal promoters to image a variety of cancers. We have also worked with intramural investigators at NIDA to enhance translation of designer receptors exclusively activated by designer drugs (DREADD) chemogenetics.

- a. Fu D, Tanhehco Y, Chen J, Foss CA, Fox JJ, Chong J-M, Fukayama M, Sgouros G, Kowalski J, Pomper MG, Ambinder RF. Bortezomib-induced enzyme-targeted radiotherapy in herpesvirus-associated tumors. *Nat Med* 2008; 14:1118-1122. PMID: PMC2709824.
 - b. Bhang H-E, Gabrielson KL, Laterra J, Fisher PB, Pomper MG. Tumor-Specific Imaging through Progression Elevated Gene-3 Promoter-Driven Gene Expression. *Nat Med* 2011; 17:123-129. PMID: PMC3057477.
 - c. Bhatnager A, Wang Y, Mease RC, Gabrielson M, Sysa P, Minn P, Green G, Simmons B, Gabrielson K, Fisher PB, Pomper MG. Astrocyte elevated gene-1 promoter-mediated imaging of prostate cancer. *Cancer Res* 2014; 74:5772-81. PMID: PMC4234089.
 - d. Gomez JL, Bonaventura J, Lesniak W, Mathews WB, Sysa-Shah P, Rodriguez LA, Ellis RJ, Richie CT, Harvey BK, Dannals RF, Pomper MG, Bonci A, Michaelides M. Chemogenetics revealed: DREADD occupancy and activation *via* converted clozapine. *Science* 2017; 357:503-507.
4. *Imaging CNS disease.* We increasingly find that molecular and cellular targets for cancer can overlap with those for neurological disease, particularly in the context of neuroinflammation, and that with imaging we can pivot between these two disease entities. An example is the case of imaging microglia *via* targeting CSF1R, noted above, which we also intend to use for detecting glioblastoma centrally, infections in the periphery or inflammatory underpinnings of neuropsychiatric disorders. Other agents target specific brain cell populations (glial cells), enzymes, receptors, all of which may report on neuroinflammation or, in some cases, neuronal activity.
- a. Coughlin JM, Wang Y, Minn I, Bienko N, Ambinder EB, Xu X, Peters ME, Dougherty JW, Vranesic M, Koo SM, Ahn H-H, Lee M, Cottrell C, Sair HI, Sawa A, Munro CA, Nowinski CJ, Dannals RF, Lyketsos CG, Kassiou M, Smith G, Caffo B, Mori S, Guilarte TR, Pomper MG. Imaging of glial cell activation and white matter integrity in the brains of active and recently retired national football league players. *JAMA Neurol* 2016; 74:67-74. PMID: PMC5504689.
 - b. Horti AG, Wang Y, Minn I, Lan X, Wang J, Koehler K, Alkayed N, Dannals RF, Pomper MG. ¹⁸F-FNDP for PET imaging of soluble epoxide hydrolase (sEH). *J Nucl Med* 2016; 57:1817-1822. PMID: PMC5095511.
 - c. Coughlin JM, Du Y, Crawford JL, Rubin LH, Behnam Azad B, Lesniak WG, Horti AG, Schretlen DJ, Sawa A, Pomper MG. The availability of the $\alpha 7$ nicotinic acetylcholine receptor in recent-onset psychosis: a study using ¹⁸F-ASEM. *J Nucl Med* 2018 Dec 20. doi: 10.2967/jnumed.118.213686.
 - d. Bonaventura J, Eldridge MA, Hu F, Gomez JL, Sanchez-Soto M, Abramyan AM, Lam S, Boehm M, Ruiz C, Farrell M, Shrestha SS, Telu S, Zoghbi SS, Gladding RL, Moreno A, Faress ISG, Andersen N, Lin JH, Pike VW, Innis RB, Moaddel R, Morris P, Shi L, Sibley DR, Mahler SV, Nabavi S, Pomper MG, Bonci A, Horti AG, Richmond BJ, Michaelides M. Chemogenetic ligands for translational neurotheranostics. *Nat Commun* 2019; 10:4627. PMID: PMC6788984.

Complete List of Published Work in MyBibliography:

<https://pubmed.ncbi.nlm.nih.gov/?term=Pomper+MG&sort=date>

D. Additional Information: Research Support

Ongoing Research Support

R01 CA184228 Pomper (contact) and Zalutsky (PI)

05/01/2014-01/31/2024

Small Molecule PSMA-Targeted Alpha Therapy

Description of Goals: Major goals of this proposal are to show that the LMW, ²¹¹At-labeled agents we propose will enable high tumor penetration and limit toxicity to normal tissues.

Role: Co-PI

R01 CA134675 Pomper (PI) 07/01/2008-08/31/2024
High-Specificity Imaging Agents for Aggressive Prostate Cancer
Description of Goals: The goals of this project are to leverage existing but untested agents and to develop new agents for imaging prostate cancer, with a focus on aggressive, localized disease.
Role: PI

T32 EB006351 Pomper (PI) 04/01/2018-03/31/2023
Training for Clinician Scientists in Imaging Research
Description of Goals: The objectives are to provide at least one dedicated year of protected research time to clinicians interested in technology platform development or projects related to brain imaging.
Role: PI

P41 EB024495 Pomper (PI) 09/15/2017-06/30/2022
Resource for Molecular Imaging Agents in Precision Medicine
Description of Goals: The objectives are to develop and disseminate new imaging agents in cancer, inflammation and immunity for a variety of modalities.
Role: PI

R33 AG054802 Pomper (PI) 05/15/2019-02/28/2021
PET imaging of soluble epoxide hydrolase (sEH) in human subjects
Description of Goals: Continuation of the R21 (chemistry) where we have begun human brain imaging studies with the agent [¹⁸F]FNNDP.
Role: PI

Completed Research Support

R24/U24 CA092871 Pomper (PI) 08/27/2001-02/28/2013
Small Animal Imaging Resource Program (SAIRP)
Description of Goals: The SAIRP was a transdisciplinary molecular imaging program that established several modalities and agents in cancer molecular imaging research and development at Johns Hopkins.
Role: PI

U54 CA151838 Searson (contact) and Pomper (PIs) 08/25/2010-07/31/2016
Center of Cancer Nanotechnology Excellence at Johns Hopkins
Description of Goals: The objective of the Center is to integrate nanotechnology-based diagnostic and therapeutic tools for comprehensive cancer care.
Role: co-PI

R01 CA138636 Pomper (contact) and Ambinder (PIs) 04/01/2010-02/29/2016
BETR Therapy for Herpesvirus-associated Tumors
Description of Goals: The purpose is to treat gammaherpesvirus-associated tumors with [¹³¹I]FIAU in patients.
Role: co-PI

P50 CA103175 Bhujwala (PI) 09/22/2011-07/31/2016
JHU ICMIC Program
Description of Goals: This center grant funds is In vivo Cellular and Molecular Imaging Center at Johns Hopkins. The program consists of four research components, four developmental projects, one career development award and four resources.
Role: Associate Director

U01 CA183031 Pomper (contact) and DeWeese (PIs) 07/14/2015-06/30/2018
PSMA directed imaging of prostate cancer: Focus on androgen receptor dynamics
Description of Goals: To leverage PSMA-targeted imaging for management of prostate cancer, e.g., via stereotactic radiotherapy and further understanding of PSMA imaging during anti-androgen therapy.
Role: co-PI

NSF BIOGRAPHICAL SKETCH

NAME: IDEKER, TREY

POSITION TITLE & INSTITUTION: Professor, UC San Diego

(a) PROFESSIONAL PREPARATION

INSTITUTION	LOCATION	MAJOR / AREA OF STUDY	DEGREE (if applicable)	YEAR YYYY
Massachusetts Institute of Technology	Cambridge, MA	Electrical Engineering & Computer Science	BS	1994
Massachusetts Institute of Technology	Cambridge, MA	Electrical Engineering & Computer Science	MENG	1995
University of Washington	Seattle, WA	Molecular Biotechnology	PHD	2001
Whitehead Institute for Biomedical Research	Cambridge, MA	Pfizer Fellow of Computational Biology	Fellow	2001 - 2003

(b) APPOINTMENTS

2010 - present Professor, UC San Diego, Division of Genetics, La Jolla, CA
2018 - present Co-Director, UC San Diego, Graduate Program in Bioinformatics, La Jolla, CA
2010 - present Adjunct Professor, UC San Diego, Department of Bioengineering, La Jolla, CA
2006 - present Adjunct Professor, UC San Diego, Computer Science & Engineering, La Jolla, CA
2009 - 2014 Division Chief, UC San Diego, Genetics, Department of Medicine, La Jolla, CA
2006 - 2010 Associate Professor, UC San Diego, Department of Bioengineering, La Jolla, CA
2003 - 2006 Assistant Professor, UC San Diego, Department of Bioengineering, La Jolla, CA

(c) PRODUCTS

Products Most Closely Related to the Proposed Project

1. Kuenzi BM, Park J, Fong SH, Sanchez KS, Lee J, Kreisberg JF, Ma J, Ideker T. Predicting Drug Response and Synergy Using a Deep Learning Model of Human Cancer Cells. *Cancer Cell*. 2020 Nov 9;38(5):672-684.e6. PubMed PMID: [33096023](#).
2. Yu MK, Ma J, Fisher J, Kreisberg JF, Raphael BJ, Ideker T. Visible Machine Learning for Biomedicine. *Cell*. 2018 Jun 14;173(7):1562-1565. PubMed PMID: [29906441](#); PubMed Central PMCID: [PMC6483071](#).
3. Ma J, Yu MK, Fong S, Ono K, Sage E, Demchak B, Sharan R, Ideker T. Using deep learning to model the hierarchical structure and function of a cell. *Nat Methods*. 2018 Apr;15(4):290-298. PubMed PMID: [29505029](#); PubMed Central PMCID: [PMC5882547](#).
4. Yu MK, Kramer M, Dutkowski J, Srivas R, Licon K, Kreisberg J, Ng CT, Krogan N, Sharan R, Ideker T. Translation of Genotype to Phenotype by a Hierarchy of Cell Subsystems. *Cell Syst*. 2016 Feb 24;2(2):77-88. PubMed PMID: [26949740](#); PubMed Central PMCID: [PMC4772745](#).
5. Dutkowski J, Kramer M, Surma MA, Balakrishnan R, Cherry JM, Krogan NJ, Ideker T. A gene ontology inferred from molecular networks. *Nat Biotechnol*. 2013 Jan;31(1):38-45. PubMed PMID:

[23242164](#); PubMed Central PMCID: [PMC3654867](#).

Other Significant Products, Whether or Not Related to the Proposed Project

1. van de Haar J, Canisius S, Yu MK, Voest EE, Wessels LFA, Ideker T. Identifying Epistasis in Cancer Genomes: A Delicate Affair. *Cell*. 2019 May 30;177(6):1375-1383. PubMed PMID: [31150618](#); PubMed Central PMCID: [PMC6816465](#).
2. Fong SH, Carlin DE, Ozturk K, Ideker T. Strategies for Network GWAS Evaluated Using Classroom Crowd Science. *Cell Syst*. 2019 Apr 24;8(4):275-280. PubMed PMID: [31022372](#); PubMed Central PMCID: [PMC6764759](#).
3. Pratt D, Chen J, Welker D, Rivas R, Pillich R, Rynkov V, Ono K, Miello C, Hicks L, Szalma S, Stojmirovic A, Dobrin R, Braxenthaler M, Kuentzer J, Demchak B, Ideker T. NDEx, the Network Data Exchange. *Cell Syst*. 2015 Oct 28;1(4):302-305. PubMed PMID: [26594663](#); PubMed Central PMCID: [PMC4649937](#).
4. Shannon P, Markiel A, Ozier O, Baliga NS, Wang JT, Ramage D, Amin N, Schwikowski B, Ideker T. Cytoscape: a software environment for integrated models of biomolecular interaction networks. *Genome Res*. 2003 Nov;13(11):2498-504. PubMed PMID: [14597658](#); PubMed Central PMCID: [PMC403769](#).
5. Ideker T, Thorsson V, Ranish JA, Christmas R, Buhler J, Eng JK, Bumgarner R, Goodlett DR, Aebersold R, Hood L. Integrated genomic and proteomic analyses of a systematically perturbed metabolic network. *Science*. 2001 May 4;292(5518):929-34. PubMed PMID: [11340206](#).

(d) SYNERGISTIC ACTIVITIES

1. Explainable Machine Learning: Guided construction of machine learning models for genotype-to-phenotype prediction (Ref RS#4); Developed DCell, which modeled subsystems in yeast and translated gene disruptions to cell proliferation phenotypes (Refs RS#2,3); Created deep neural network of a cancer cell which predicts response to therapy (Ref RS#1); Used omics data to infer an ontology of components within eukaryotic cells and their hierarchical relationships (Ref RS#5)
2. Software: Cytoscape (Ref OS#4) platform for analysis of biomolecular interaction networks (>20k citations); Network Data Exchange (NDEx) database and community for sharing networks
3. Foundational Publication in Systems Biology: Leroy Hood and I, as his trainee, published a proof-of-principle paper outlining the "systems approach" to biological systems (Ref OS#5). It was the first work to integrate multiple 'omics data sets (mRNA profiles, proteomics, protein networks).
4. Leadership, Service, and Teaching: NIH NHGRI Advisory Council (2016-present); Conference Committees: ISMB, PSB and RECOMB (2006-present); Ad-hoc Reviewer: NSF (2004-2016); NIH Biodata Management and Analysis Study Section (2007-2012); Reviewer: EU Sixth Framework Grant Programme (2005-2006); Journal Editorial Boards: *Cell*, *Cell Systems*, *Cell Reports*, *PLoS Computational Biology*, *Molecular Systems Biology*, *DNA Repair*, and *Scientific Data*. Teaching: "Network Biology" (MED283) graduate course, which has furthered ideas in classroom challenge competitions and crowd science (Ref OS#2)



Joya Delgado Harris, MPH

As Director, Research Integration at the American Cancer Society, Joya provides oversight and management of the integration of program outcomes of the *Office of Cancer Research and Implementation* into enterprise-wide organization and mission objectives.

Prior to this role, Joya worked for Y-ME National Breast Cancer Organization. Initially, serving as the Executive Director of the Southeast Region Affiliate, she later assumed an expanded role as Director of Public Policy and Community Relations. In this role she helped set goals in policy, programs, and partnerships.

As a Stage 3C breast cancer survivor, Joya is very passionate about the importance of disseminating research results to the medical community from the patient perspective. She recognizes the importance of bridging the gap that often exists between the science and the impact, by furthering the understanding of the real-life application between what happens in the laboratory and how it will affect the patient.

From 2011-2016, Joya was appointed to the National Cancer Institute's *Council of Research Advocates*, a Federal Advisory Committee that provides counsel to the Director of the National Cancer Institute on relevant, non-scientific issues. Joya is also a graduate of the Research Advocacy Network's *Focus on Research Scholar* program, a network of advocates and researchers who influence cancer research through collaboration, education, and mutual support. Joya also serves as a Consumer Peer Reviewer for the Congressionally Directed Medical Research Programs (CDMRP), administered by the Department of Defense, to review and evaluate innovative breast cancer research grant proposals.

Joya earned a BA from Wellesley College, and received a Masters of Public Health degree with concentration in public health policy and management from the Rollins School of Public Health of Emory University.

JOYA DELGADO HARRIS, MPH

Results-driven, performance-based, and team-spirited leader with extensive non-profit management experience and demonstrated accomplishments in key leadership functions. Significant background executing transformational direction towards achieving measurable and strategic goals *Core competencies* include thought-leadership, program development, implementation, and evaluation; curriculum design; grant-writing and resource development; board cultivation and management; developing and stewarding business partnerships; proficient in Spanish. *Career focus areas* include cancer, youth leadership development; behavioral health and developmental disabilities; health education/promotion; and safety/emergency preparedness.

PROFESSIONAL EXPERIENCE

American Cancer Society, Atlanta, GA **Director, Research Integration**

Nov 2012 – present

Provide oversight and management of the integration of the outcomes of the Office of the Chief Medical and Scientific Officer into enterprise-wide organization and mission objectives. Lead relationships between Extramural Grants, Population Science, Data Science, Patient Delivery, and Cancer Care & Survivorship departments and other Society business units; integrate the departments' mission roles and objectives into enterprise wide strategic processes; provide oversight of special initiatives – constituent engagement and funding – to maintain a strong customer-focused environment.

Y-ME National Breast Cancer Organization, Atlanta, GA **Director – Public Policy and Community Relations**

Jan 2011 – July 2011

Directed the organization's patient advocacy and community programs in alignment with the core mission. Worked closely with senior leadership to help set strategic goals in policy, community health, programs, and partnerships. Developed and implemented plans for educating and activating Y-ME constituents and partners on priority issues that affect breast cancer patients and ensures that public policy efforts are integrated with other Y-ME strategic priorities.

Executive Director, Southeast Region

Nov 2008 – Jan 2011

Directed and oversaw all affiliate relations for the Southeast Region for Chicago-based breast cancer support organization including administration and management, development and marketing, program management, advocacy, and board development. Managed development activities including annual *Walk to Empower*, corporate sponsorships, family and corporate team fundraising.

Association of Village PRIDE, Inc., Atlanta, GA **Executive Director**

Aug 2005-July 2008

Consultant position (hired by and reported directly to 11-person Board of Directors) providing strategic direction, tactical planning and outreach for community-based youth leadership organization serving Fayette County. Provided oversight to 4 Program Coordinators.

- Increased student retention by 14% (versus prior year) by implementing innovative and cost-effective programs that provide valuable learning experiences for students.
- Directed fundraising efforts, mailing campaigns, grant writing, and other solicitation activities.
- Established open lines of communication between stakeholders including parents, students, schools, community and Board of Directors to grow the organization's influence and capabilities.
- Developed and expanded community and business partnerships that create service, education and/or internship opportunities for students. Key relationships INROADS Atlanta, Fayette County Chamber of Commerce, Georgia Department of Labor, Fayette Factor, The Community Foundation of Fayette County, United Way of Metro Atlanta, and Fayetteville Barnes & Noble.
- Managed the Family Learning Resource Center and after-school programs, Reading Right and BRIDGES (for elementary and middle school students), at Harmony Village Apartment complex in Peachtree City. In collaboration with Harmony Properties, Oak Grove Elementary School, and Rising Starr Middle School, oversaw programs that provided academic support for youth.

American Red Cross, Atlanta, GA
Director of Product Development

March 2001-Oct 2003

Managed the implementation and evaluation of youth and education program initiatives in the Southeast's headquarter location for one of the country's largest and most trusted charity organizations.

- Generated approximately \$200k in *incremental* State funding through the identification and alignment of existing health, science and physical education programs to the Quality Core Curriculum guidelines established by the Georgia Board of Education.
- Developed content and introduced 12 new course curricula and supporting teaching materials in English and Spanish to address unmet community and school needs in leadership, conflict resolution, decision-making, first aid, disaster preparedness, healthy eating, and senior support.
- Selected by senior management to create the *first* strategic corporate outreach program with BellSouth.
- Recognized and commended for leadership and commitment demonstrated in the aftermath of September 11th by local and national management.

Progressive Youth Homes, Atlanta, GA
Co-Director

Nov 1997-Jul 1998

Oversaw implementation and operations for a new full-service group home licensed to provide foster care for 6 boys ages 8-17.

- Trained 3 person staff in child care regulations and compliance requirements to create and maintain a safe and healthy home environment.
- Teamed with educators, case workers and therapists to determine each child's specific needs and monitor progress.

Fulton County Health Department, Atlanta, GA
Public Health Educator/Research Assistant

Sep 1994-Jun 1995

Worked with existing county programs and the implementation and training of new programs in the office of Community Health Planning.

- Trained, managed and mentored 5 community members as health educators as part of an innovative pregnancy prevention and healthy start program.
- Successfully solicited donations to cover venue and all other expenses associated with *Healthy Moms-Healthy Babies* one-day event.
- Analyzed and interpreted statistical data in the preparation of a special management study assessing efficiency and effectiveness of the division.

EDUCATION

Emory University, Atlanta, GA

Master of Public Health, concentration in Health Policy/Management

Wellesley College, Wellesley, MA

Bachelor of Arts, major in Spanish, minor in Biology

MEMBERSHIPS/COMMUNITY INVOLVEMENT

Board Member/Independent Director, Concierge Technologies

Former Board Member, *NCI Council of Research Advocates* (National Cancer Institute)

Focus on Research Scholar, Research Advocacy Network

Member, American Public Health Association

Immediate Past President, Atlanta Wellesley Club (College Alumnae Chapter)



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: KRISTEN PAULING DOYLE, DEPUTY EXECUTIVE OFFICER &
GENERAL COUNSEL
CAMERON L. ECKEL, STAFF ATTORNEY
SUBJECT: CHAPTER 703 RULE CHANGES PROPOSED FOR FINAL ADOPTION
DATE: FEBRUARY 5, 2021

Summary and Recommendation

The Board Governance Subcommittee recommends that the Oversight Committee adopt the proposed administrative rule changes to Chapter 703 as originally considered at the November 18, 2020, meeting. Once the Oversight Committee approves the final order adopting the rule changes, CPRIT will submit the amendments to the Secretary of State and the changes will be effective 20 days later.

Discussion

State law requires an agency to set policy using a rulemaking process, which includes an opportunity for public comment on proposed rules and rule changes before the agency formally adopts the policy. The *Texas Register* published the proposed amendments in its December 4, 2020, edition. CPRIT did not receive any comments on the proposed rules from the public.

The amendment to § 703.3(b)(4) clarifies that in the Request for Applications, the Institute may specify the minimum level of effort, if any, that a Principal Investigator, co-Principal Investigator, or other specified key personnel must maintain for the grant project. The change to § 703.26(e)(12) clarifies that CPRIT will not reimburse professional association membership fees or dues for an individual employed by a grant recipient. However, membership fees or dues paid by the grant recipient for the entity's membership in business, technical, and professional organizations may be an allowable expense.

The Board Governance Subcommittee met on February 4 to review the final order with CPRIT's General Counsel. The Subcommittee recommends the Oversight Committee approve the final order adopting the proposed rule changes.

Next Steps

After the Oversight Committee adopts the proposed rule changes, CPRIT will submit the final order to the Secretary of State. The rule changes become effective 20 days after the date CPRIT files the order with the Secretary of State.

The Cancer Prevention and Research Institute of Texas (“CPRIT” or “the Institute”) adopts the amendments to 25 Tex. Admin. Code §§703.3(b)(4) and 703.26(e)(12) without changes to the proposed amendments as published in the December 4, 2020, issue of the Texas Register (45 TexReg 8726); therefore, the rules will not be republished. The amendments relate to Request for Applications content and reimbursement of a grant recipient’s professional association dues and fees.

Reasoned Justification

The amendment to § 703.3(b)(4) clarifies that in the Request for Applications, the Institute may specify the minimum level of effort, if any, that a Principal Investigator, co-Principal Investigator, or other specified key personnel must maintain for the grant project. The change to § 703.26(e)(12) clarifies that professional association membership fees or dues for an individual employed by a grant recipient are not allowable for reimbursement. However, membership fees or dues paid by the grant recipient for the entity’s membership in business, technical, and professional organizations may be an allowable expense.

Summary of Public Comments and Staff Recommendation

CPRIT received no public comments regarding the proposed amendments to §§ 703.3(b)(4) and 703.26(e)(12).

The rule changes are adopted under the authority of the Texas Health and Safety Code Annotated, § 102.108, which provides the Institute with broad rule-making authority to administer the chapter, including rules for awarding grants.

Certification

The Institute hereby certifies that Kristen Pauling Doyle, General Counsel, reviewed the adoption of the rules and found it to be a valid exercise of the agency’s legal authority.

To be filed with the Office of Secretary of State on February 19, 2021.

<rule>

§703.3. Grant Applications.

(a) The Institute shall accept Grant Applications for Cancer Research and Cancer Prevention programs to be funded by the Cancer Prevention and Research Fund or the proceeds of general obligation bonds issued on behalf of the Institute in response to standard format Requests for Applications issued by the Institute.

(b) Each Request for Applications shall be publicly available through the Institute's Internet website. The Institute reserves the right to modify the format and content requirements for the Requests for Applications from time to time. Any modifications will be available through the Institute's Internet website. The Request for Applications shall:

(1) Include guidelines for the proposed projects and may be accompanied by instructions provided by the Institute.

(2) State the criteria to be used during the Grant Review Process to evaluate the merit of the Grant Application, including guidance regarding the range of possible scores.

(A) The specific criteria and scoring guidance shall be developed by the Chief Program Officer in consultation with the Review Council.

(B) When the Institute will use a preliminary evaluation process as described in §703.6 of this chapter (relating to Grant Review Process) for the Grant Applications submitted pursuant to a particular Grant Mechanism, the Request for Applications shall state the criteria and Grant Application components to be included in the preliminary evaluation.

(3) Specify limits, if any, on the number of Grant Applications that may be submitted by an entity for a particular Grant Mechanism to ensure timely and high-quality review when a large number of Grant Applications are anticipated.

(4) Specify the minimum level of effort, if any, for the Principal Investigator, co-Principal Investigator, and other specified key personnel of an entity approved for a Grant Award.

(c) Requests for Applications for Cancer Research and Cancer Prevention projects issued by the Institute may address, but are not limited to, the following areas:

(1) Basic research;

(2) Translational research, including proof of concept, preclinical, and Product Development activities;

(3) Clinical research;

(4) Population based research;

(5) Training;

(6) Recruitment to the state of researchers and clinicians with innovative Cancer Research approaches;

(7) Infrastructure, including centers, core facilities, and shared instrumentation;

(8) Implementation of the Texas Cancer Plan; and

(9) Evidence based Cancer Prevention education, outreach, and training, and clinical programs and services.

(d) An otherwise qualified applicant is eligible solely for the Grant Mechanism specified by the Request for Applications under which the Grant Application was submitted.

(e) The Institute may limit the number of times a Grant Application not recommended for a Grant Award during a previous Grant Review Cycle may be resubmitted in a subsequent Grant

Review Cycle. The Request for Applications will state the resubmission guidelines, including specific instructions for resubmissions.

(f) Failure to comply with the material and substantive requirements set forth in the Request for Applications may serve as grounds for disqualification from further consideration of the Grant Application by the Institute. A Grant Application determined by the Institute to be incomplete or otherwise noncompliant with the terms or instructions set forth by the Request for Applications shall not be eligible for consideration of a Grant Award.

(g) Only those Grant Applications submitted via the designated electronic portal designated by the Institute by the deadline, if any, stated in the Request for Applications shall be eligible for consideration of a Grant Award.

(1) Nothing herein shall prohibit the Institute from extending the submission deadline for one or more Grant Applications upon a showing of good cause, as determined by the Chief Program Officer.

(2) A request to extend the Grant Application submission deadline must be in writing and sent to the CPRIT Helpdesk via electronic mail, within 24 hours of the submission deadline.

(3) The Institute shall document any deadline extension granted, including the good cause for extending the deadline and will cause the documentation to be maintained as part of the Grant Review Process records.

(h) The Grant Applicant shall certify that it has not made and will not make a donation to the Institute or any foundation created to benefit the Institute.

(1) Grant Applicants that make a donation to the Institute or any foundation created to benefit the Institute on or after June 14, 2013, are ineligible to be considered for a Grant Award.

(2) For purposes of the required certification, the Grant Applicant includes the following individuals or the spouse or dependent child(ren) of the following individuals:

(A) the Principal Investigator, Program Director, or Company Representative;

(B) a Senior Member or Key Personnel listed on the Grant Application; and

(C) an officer or director of the Grant Applicant.

(3) Notwithstanding the foregoing, one or more donations exceeding \$500 by an employee of a Grant Applicant not described by paragraph (2) of this subsection shall be considered to be made on behalf of the Grant Applicant for purposes of the certification.

(4) The certification shall be made at the time the Grant Application is submitted.

(5) The Chief Compliance Officer shall compare the list of Grant Applicants to a current list of donors to the Institute and any foundation created to benefit the Institute.

(6) To the extent that the Chief Compliance Officer has reason to believe that a Grant Applicant has made a donation to the Institute or any foundation created to benefit the Institute, the Chief

Compliance Officer shall seek information from the Grant Applicant to resolve any issue. The Grant Application may continue in the Grant Review Process during the time the additional information is sought and under review by the Institute.

(7) If the Chief Compliance Officer determines that the Grant Applicant has made a donation to the Institute or any foundation created to benefit the Institute, then the Institute shall take appropriate action. Appropriate action may entail:

(A) Withdrawal of the Grant Application from further consideration; or

(B) Return of the donation, if the return of the donation is possible without impairing Institute operations.

(8) If the donation is returned to the Applicant, then the Grant Application is eligible to be considered for a Grant Award.

(i) Grant Applicants shall identify by name all sources of funding contributing to the project proposed for a Grant Award. A Grant Applicant for a Product Development Research Grant Award must provide a capitalization table that includes those individuals or entities that have an investment, stock or rights in the company. The Institute shall make the information provided by the Grant Applicant available to Scientific Research and Prevention Programs Committee members, Institute employees, independent contractors participating in the Grant Review Process, Program Integration Committee Members and Oversight Committee Members for purposes of identifying potential Conflicts of Interest prior to reviewing or taking action on the Grant Application. The information shall be maintained in the Institute's Grant Review Process records.

(j) A Grant Applicant shall indicate if the Grant Applicant is currently ineligible to receive Federal or State grant funds due to debarment or suspension or if the Grant Applicant has had a grant terminated for cause within five years prior to the submission date of the Grant Application. For purposes of the provision, the term Grant Applicant includes the personnel, including collaborators or contractors, who will be working on the Grant Award. A Grant Applicant is not eligible to receive a Grant Award if the Grant Applicant is debarred, suspended, ineligible or otherwise excluded from participation in a federal or state grant award.

(k) The Institute may require each Grant Applicant for a Cancer Research Grant Award for Product Development to submit an application fee.

(1) The Chief Executive Officer shall adopt a policy regarding the application fee amount.

(2) The Institute shall use the application fee amounts to defray the Institute's costs associated with the Product Development review processes, including due diligence and intellectual property reviews, as specified in the Request for Application.

(3) Unless a request to submit the fee after the deadline has been approved by the Institute, the Institute may administratively withdraw a Grant Application if the application review fee is not received by the Institute within seven business days of the Grant Application submission deadline.

(4) Upon a written request from the Grant Applicant, the Institute may refund the application fee to the Grant Applicant if the Grant Applicant withdraws the Grant Application or the Grant Application is otherwise removed from the Grant Review Process prior to the review of the Grant Application by the Scientific Research and Prevention Programs Committees. The Institute's decision regarding return of the application fee is final.

(l) During the course of administrative review of the Grant Application, the Institute may contact the Grant Applicant to seek clarification on information provided in the Grant Application or to request additional information if such information clarifies the Grant Application. The Institute shall keep a record of requests made under this subsection for review by the Chief Compliance Officer.

§703.26. Allowable Costs.

(a) A cost is an Allowable Cost and may be charged to the Grant Award if it is reasonable, allocable, and adequately documented.

(1) A cost is reasonable if the cost does not exceed that which would be incurred by a prudent individual or organization under the circumstances prevailing at the time the decision was made to incur the cost; and is necessary for the performance of the Grant Award defined in the Scope of Work in the Grant Contract.

(2) A cost is allocable if the cost:

(A) Benefits the Grant Award either directly or indirectly, subject to Indirect Cost limits stated in the Grant Contract;

(B) Is assigned the Grant Award in accordance with the relative benefit received;

(C) Is allowed or not prohibited by state laws, administrative rules, contractual terms, or applicable regulations;

(D) Is not included as a cost or used to meet Matching Fund requirements for any other Grant Award in either the current or a prior period; and

(E) Conforms to any limitations or exclusions set forth in the applicable cost principles, administrative rules, state laws, and terms of the Grant Contract.

(3) A cost is adequately documented if the cost is supported by the organization's accounting records and documented consistent with §703.24 of this title (relating to Financial Status Reports).

(b) Grant Award funds must be used for Allowable Costs as provided by the terms of the Grant Contract, Chapter 102, Texas Health and Safety Code, the Institute's administrative rules, and the Uniform Grant Management Standards (UGMS) adopted by the Comptroller's Office. If guidance from the Uniform Grant Management Standards on a particular issue conflicts with a specific provision of the Grant Contract, Chapter 102, Texas Health and Safety Code or the Institute's administrative rules, then the Grant Contract, statute, or Institute administrative rule shall prevail.

(c) An otherwise Allowable Cost will not be eligible for reimbursement if the Grant Recipient incurred the expense outside of the Grant Contract term, unless the Grant Recipient has received written approval from the Institute's Chief Executive Officer to receive reimbursement for expenses incurred prior to the effective date of the Grant Contract.

(d) An otherwise Allowable Cost will not be eligible for reimbursement if the benefit from the cost of goods or services charged to the Grant Award is not realized within the applicable term of the Grant Award. The Grant Award should not be charged for the cost of goods or services that benefit another Grant Award or benefit a period prior to the Grant Contract effective date or after the termination of the Grant Contract.

(e) Grant Award funds shall not be used to reimburse unallowable expenses, including, but not limited to:

(1) Bad debt, such as losses arising from uncollectible accounts and other claims and related costs.

(2) Contributions to a contingency reserve or any similar provision for unforeseen events.

(3) Contributions and donations made to any individual or organization.

(4) Costs of entertainment, amusements, social activities, and incidental costs relating thereto, including tickets to shows or sports events, meals, alcoholic beverages, lodging, rentals, transportation and gratuities.

(5) Costs relating to food and beverage items, unless the food item is related to the issue studied by the project that is the subject of the Grant Award.

(6) Fines, penalties, or other costs resulting from violations of or failure to comply with federal, state, local or Indian tribal laws and regulations.

(7) An honorary gift or a gratuitous payment.

(8) Interest and other financial costs related to borrowing and the cost of financing.

(9) Legislative expenses such as salaries and other expenses associated with lobbying the state or federal legislature or similar local governmental bodies, whether incurred for purposes of legislation or executive direction.

(10) Liability insurance coverage.

(11) Benefit replacement pay or legislatively-mandated pay increases for eligible general revenue-funded state employees at Grant Recipient state agencies or universities.

(12) Professional association fees or dues for an individual employed by the Grant Recipient. Professional association fees or dues for the Grant Recipient's membership in business, technical, and professional organizations may be allowed, with prior approval from the Institute, if:

(A) the professional association is not involved in lobbying efforts; and

(B) the Grant Recipient demonstrates how membership in the professional association benefits the Grant Award project(s). [~~or an individual~~]

(13) Promotional items and costs relating to items such as T-shirts, coffee mugs, buttons, pencils, and candy that advertise or promote the project or Grant Recipient.

(14) Fees for visa services.

(15) Payments to a subcontractor if the subcontractor working on a Grant Award project employs an individual who is a Relative of the Principal Investigator, Program Director, Company Representative, Authorized Signing Official, or any person designated as Key Personnel for the same Grant Award project (collectively referred to as "affected Relative"), and:

(A) the Grant Recipient will be paying the subcontractor with Grant Award funds for any portion of the affected Relative's salary; or

(B) the Relative submits payment requests on behalf of the subcontractor to the Grant Recipient for payment with Grant Award funds.

(C) For exceptional circumstances, the Institute's Chief Executive Office may grant an exception to allow payment of Grant Award funds if the Grant Recipient notifies the Institute prior to finalizing the subcontract. The Chief Executive Officer must notify the Oversight Committee in writing of the decision to allow reimbursement for the otherwise unallowable expense.

(D) Nothing herein is intended to supersede a Grant Recipient's internal policies, to the extent that such policies are stricter.

(16) Fundraising.

(17) Tips or gratuities.

(f) The Institute is responsible for making the final determination regarding whether an expense shall be considered an Allowable Cost.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: KRISTEN PAULING DOYLE, DEPUTY EXECUTIVE OFFICER &
GENERAL COUNSEL
CAMERON L. ECKEL, ASSISTANT GENERAL COUNSEL

SUBJECT: CHAPTERS 702 AND 703 - PROPOSED RULE CHANGES

DATE: FEBRUARY 5, 2021

Summary and Recommendation

The Board Governance Subcommittee met February 4 and recommends that the Oversight Committee approve two proposed administrative rule changes for publication in the *Texas Register*. The suggested changes affect Texas Administrative Code Chapters 702 and 703. Publication of the anticipated rule changes in the *Texas Register* is the first step in the agency rulemaking process. CPRIT Staff will bring back the proposed rules and any public comments to the Oversight Committee in May for final approval.

Discussion

CPRIT's administrative rules set policy guiding CPRIT's grant review and grant contracting processes as well as managing other requirements of Texas Health and Safety Code Chapter 102. State law requires agencies to use a rulemaking process, which includes an opportunity for the public to comment on the rule changes before the agency adopts the final policy.

The Board Governance Subcommittee met on February 4 to discuss the proposed rule changes to §§ 702.19(b) and 703.10(c)(3) with CPRIT staff. The subcommittee voted to recommend that the Oversight Committee approve the following suggested rule changes for publication.

- The proposed change to § 702.19(b) provides a limited exception to the general communication prohibition between a grant applicant and a peer reviewer. (CPRIT's administrative rules refer to peer reviewers by the term used in the statute – a "Scientific Research and Prevention Programs Committee" member.) The exception allows a peer reviewer assigned by the Product Development Review Council (PDRC) Chairperson to participate in the interview with the applicant during the business and operations and/or intellectual property due diligence review. Assigning a peer reviewer to directly interact with a grant applicant during this stage of review helps to ensure that the PDRC has all the information it needs to evaluate a grant application. All grant applicants that reach due diligence review will be subject to the same process.

- The proposed change to 703.10(c)(3) requires a grantee to include CPRIT grant identification numbers in the acknowledgement of CPRIT funding. CPRIT requires all grant recipients to acknowledge CPRIT funding in any publication.

Next Steps

Once approved by the Oversight Committee, CPRIT will publish the proposed rule changes in the *Texas Register*. The publication date begins the 30-day period for soliciting comment from interested members of the public. CPRIT will also post the proposed rule changes on our website and announce the opportunity for public comment via CPRIT's electronic list serve. CPRIT legal staff will summarize any comments received from the public for the Oversight Committee's consideration when approving the final rule changes in May.

The Cancer Prevention and Research Institute of Texas (“CPRIT” or “the Institute”) proposes an amendment to 25 Tex. Admin. Code § 702.19(b) allowing a narrow exception to the general communication prohibition between a grant applicant and a member of the Scientific Research and Prevention Programs Committee regarding the substance of a pending application.

Background and Justification

Until a grant applicant receives final notice regarding the outcome of a grant application, Section 702.19 prohibits discussion of the substance of a grant application between a grant applicant and a member of the Scientific Research and Prevention Programs Committee (SRPP), Program Integration Committee, and Oversight Committee. The proposed exception to Section 703.19(b) would allow an SRPP member, who is assigned by the Product Development Review Council Chairperson, to participate in the business operations and management due diligence review and intellectual property review and communicate with an applicant without violating Section 703.19. The assigned SRPP member, acting on behalf of the Product Development Review Council, member would be allowed to communicate with grant applicant and ask clarifying and substantive questions that will assist in the grant evaluation by the Product Development Review Council. All grant applicants who reach due diligence review will be subject to this proposed exception and may communicate with their assigned SRPP member without violating Section 702.19. The Institute will maintain records of SRPP members who are assigned to due diligence review.

Fiscal Note

Kristen Pauling Doyle, Deputy Executive Officer and General Counsel for the Cancer Prevention and Research Institute of Texas, has determined that for the first five-year period the rule changes are in effect, there will be no foreseeable implications relating to costs or revenues for state or local government due to enforcing or administering the rules.

Public Benefit and Costs

Ms. Doyle has determined that for each year of the first five years the rule changes are in effect the public benefit anticipated due to enforcing the rules will be clarification regarding the required level of effort required for personnel working on grant projects, and the reimbursement status of professional association membership fees or dues.

Small Business, Micro-Business, and Rural Communities Impact Analysis

Ms. Doyle has determined that the rule change will not affect small businesses, micro businesses, or rural communities.

Government Growth Impact Statement

The Institute, in accordance with 34 Texas Administrative Code §11.1, has determined that during the first five years that the proposed rule change will be in effect:

(1) the proposed rule change will not create or eliminate a government program;

- (2) implementation of the proposed rule change will not affect the number of employee positions;
- (3) implementation of the proposed rule change will not require an increase or decrease in future legislative appropriations;
- (4) the proposed rule change will not affect fees paid to the agency;
- (5) the proposed rule change will not create new rule;
- (6) the proposed rule change will not expand existing rule;
- (7) the proposed rule change will not change the number of individuals subject to the rule; and
- (8) The rule change is unlikely to have an impact on the state's economy. Although the change is likely to have neutral impact on the state's economy, the Institute lacks enough data to predict the impact with certainty.

Submit written comments on the proposed rule changes to Ms. Kristen Pauling Doyle, General Counsel, Cancer Prevention and Research Institute of Texas, P. O. Box 12097, Austin, Texas 78711, no later than April 5, 2021. The Institute asks parties filing comments to indicate whether they support the rule revision proposed by the Institute and, if a party requests a change, to provide specific text to include in the rule. Parties may submit comments electronically to kdoyle@cprit.texas.gov or by facsimile transmission to 512/475-2563.

Statutory Authority

The Institute proposes the rule change under the authority of the Texas Health and Safety Code Annotated, §102.108, which provides the Institute with broad rule-making authority to administer the chapter. Ms. Doyle has reviewed the proposed amendment and certifies the proposal to be within the Institute's authority to adopt.

There is no other statute, article, or code affected by these rules.

§702.19. Restriction on Communication Regarding Pending Grant Application.

(a) Communication regarding the substance of a pending Grant Application between the Grant Applicant and an Oversight Committee Member, a Program Integration Committee Member, or a Scientific Research and Prevention Programs Committee Member is prohibited.

(b) The prohibition on communication begins on the first day that Grant Applications for the Grant Mechanism are accepted by the Institute and extends until the Grant Applicant receives notice regarding a final decision on the Grant Application.

(1) The prohibition on communication does not apply to the time period when pre-applications or letters of interest are accepted.

(2) In special circumstances, an Oversight Committee Member or a Program Integration Committee Member may respond to a question or request for more information from a Grant Applicant so long as the response is made available to all Grant Applicants.

(3) The prohibition does not apply to a Scientific Research and Prevention Programs Committee Member who is assigned by the Product Development Review Council chairperson to participate in the business operations and management due diligence review and intellectual property review as described in Chapter 703 of this title (relating to Grants for Cancer Prevention and Research). A Scientific Research and Prevention Programs Committee Member, on behalf of the Product Development Review Council, may participate in the due diligence review process and ask clarifying questions of a Grant Applicant to gain substantive knowledge, which the Product Development Review Council will use in the review of the Grant Application.

(A) Each Grant Application recommended to the due diligence stage of review will be subject to the same review and participation by a Scientific Research and Prevention Programs Committee Member as described in paragraph (3).

(B) The Institute will maintain documentation of the Scientific Research and Prevention Programs Committee Members assigned to participate in due diligence review.

(c) Intentional, serious, or frequent violations of this rule may result in the disqualification of the Grant Applicant from further consideration for a Grant Award.

(d) This rule is not intended to prohibit open dialogue between the public and the Chief Executive Officer, a Program Integration Committee Member or a member of the Oversight Committee regarding the general status or nature of pending Grant Applications.

(e) The Chief Executive Officer may grant a waiver from the general prohibition on communication upon finding that the waiver is in the interest of promoting the objectives of the Institute and is not intended to give one or more Grant Applicants an unfair advantage. The waiver shall be provided to the Oversight Committee in writing at the time it is granted and state the reasons for the granting the waiver. The waiver shall be included as part of the public information supporting the Chief Executive Officer's affidavit(s) for Grant Award recommendations in the Grant Review Cycle(s) corresponding to the waiver.

(f) A Program Integration Committee Member shall not communicate individually with one or more Oversight Committee Members about a Grant Award recommendation for a Grant Application in a pending Grant Review Cycle until such time that the Program Integration Committee has submitted the list of Grant Award Recommendations to the Oversight Committee and the Chief Executive Officer has submitted the written affidavit required by Chapter 703, §703.7 of this title (relating to Program Integration Committee Funding Recommendation). Nothing herein shall prohibit the Chief Executive Officer or a Program Integration Committee Member from responding to an individual Oversight Committee Member's question or request for more information so long as the response is made available to all Oversight Committee Members.

The Cancer Prevention and Research Institute of Texas (“CPRIT” or “the Institute”) proposes an amendment to 25 Tex. Admin. Code § 703.10(c)(3) requiring a grant recipient to include applicable CPRIT grant identification numbers when acknowledging CPRIT funding in publications.

Background and Justification

The proposed amendment requires the grant recipient to include all applicable grant award identification number(s) when acknowledging Institute grant funding. CPRIT requires grant recipients to explicitly recognize the Institute in any publication that reports information developed with CPRIT grant funds, including scholarly publications. The change to require the grant award identification number(s) in the acknowledgement improves the Institute’s ability to track the outcome of its funded grant projects.

Section 703.10(c)(3) requires CPRIT’s grant contracts to include terms relating to a grant recipient’s acknowledgement of CPRIT funding in a publication. The proposed amendment clarifies that effective September 1, 2021, the acknowledgment of CPRIT funding must include the applicable grant identification number of every Institute funded grant that contributes to a published work. The change would allow the Institute greater ease when tracking grant funding in published scholarly articles or journals.

Fiscal Note

Kristen Pauling Doyle, Deputy Executive Officer and General Counsel for the Cancer Prevention and Research Institute of Texas, has determined that for the first five-year period the rule change is in effect, there will be no foreseeable implications relating to costs or revenues for state or local government due to enforcing or administering the rule.

Public Benefit and Costs

Ms. Doyle has determined that for each year of the first five years the rule change is in effect the public benefit anticipated due to enforcing the rule will be clarification regarding the information the grant recipient must provide when acknowledging Institute funding in publications.

Small Business, Micro-Business, and Rural Communities Impact Analysis

Ms. Doyle has determined that the rule change will not affect small businesses, micro businesses, or rural communities.

Government Growth Impact Statement

The Institute, in accordance with 34 Texas Administrative Code §11.1, has determined that during the first five years that the proposed rule change will be in effect:

- (1) the proposed rule change will not create or eliminate a government program;
- (2) implementation of the proposed rule change will not affect the number of employee positions;

- (3) implementation of the proposed rule change will not require an increase or decrease in future legislative appropriations;
- (4) the proposed rule change will not affect fees paid to the agency;
- (5) the proposed rule change will not create new rule;
- (6) the proposed rule change will not expand existing rule;
- (7) the proposed rule change will not change the number of individuals subject to the rule; and
- (8) The rule change is unlikely to have an impact on the state's economy. Although the change is likely to have neutral impact on the state's economy, the Institute lacks enough data to predict the impact with certainty.

Submit written comments on the proposed rule change to Ms. Kristen Pauling Doyle, General Counsel, Cancer Prevention and Research Institute of Texas, P. O. Box 12097, Austin, Texas 78711, no later than April 5, 2021. The Institute asks parties filing comments to indicate whether they support the rule revision proposed by the Institute and, if a party requests a change, to provide specific text to include in the rule. Parties may submit comments electronically to kdoyle@cprit.texas.gov or by facsimile transmission to 512/475-2563.

Statutory Authority

The Institute proposes the rule change under the authority of the Texas Health and Safety Code Annotated, §102.108, which provides the Institute with broad rule-making authority to administer the chapter. Ms. Doyle has reviewed the proposed amendment and certifies the proposal to be within the Institute's authority to adopt.

There is no other statute, article, or code affected by these rules.

<rule>

§703.10. Awarding Grants by Contract.

- (a) The Oversight Committee shall negotiate on behalf of the state regarding the awarding of grant funds and enter into a written contract with the Grant Recipient.
- (b) The Oversight Committee may delegate Grant Contract negotiation duties to the Chief Executive Officer and the General Counsel for the Institute. The Chief Executive Officer may enter into a written contract with the Grant Recipient on behalf of the Oversight Committee.
- (c) The Grant Contract shall include the following provisions:
 - (1) If any portion of the Grant Contract has been approved by the Oversight Committee to be used to build a capital improvement, the Grant Contract shall specify that:
 - (A) The state retains a lien or other interest in the capital improvement in proportion to the percentage of the Grant Award amount used to pay for the capital improvement; and

(B) If the capital improvement is sold, then the Grant Recipient agrees to repay to the state the Grant Award used to pay for the capital improvement, with interest, and share with the state a proportionate amount of any profit realized from the sale;

(2) Terms relating to Intellectual Property Rights and the sharing with the Institute of revenues generated by the sale, license, or other conveyance of such Project Results consistent with the standards established by this chapter;

(3) Terms relating to publication of materials created with Grant Award funds or related to the Cancer Research or Cancer Prevention project that is the subject of the Grant Award, including an acknowledgement of Institute funding and copyright ownership, if applicable;

(A) Acknowledgment of Institute funding must include the grant number of every Institute-funded grant contributing to the work memorialized in the publication.

(B) Subparagraph (A) is effective beginning September 1, 2021.

(4) Repayment terms, including interest rates, to be enforced if the Grant Recipient has not used Grant Award funds for the purposes for which the Grant Award was intended;

(5) A statement that the Institute does not assume responsibility for the conduct of the Cancer Research or Cancer Prevention project, and that the conduct of the project and activities of all investigators are under the scope and direction of the Grant Recipient;

(6) A statement that the Cancer Research or Cancer Prevention project is conducted with full consideration for the ethical and medical implications of the project and that the project will comply with all federal and state laws regarding the conduct of the Cancer Research or Prevention project;

(7) Terms related to the Standards established by the Oversight Committee in Chapter 701 of this title (relating to Policies and Procedures) to ensure that Grant Recipients, to the extent reasonably possible, demonstrate good faith effort to purchase goods and services for the Grant Award project from suppliers in this state and from historically underutilized businesses as defined by Chapter 2161, Texas Government Code, and any other state law;

(8) An agreement by the Grant Recipient to submit to regular inspection reviews of the Grant Award project by Institute staff during normal business hours and upon reasonable notice to ensure compliance with the terms of the Grant Contract and continued merit of the project;

(9) An agreement by the Grant Recipient to submit Grant Progress Reports to the Institute on a schedule specified by the Grant Contract that include information on a grant-by-grant basis quantifying the amount of additional research funding, if any, secured as a result of Institute funding;

(10) An agreement that, to the extent possible, the Grant Recipient will evaluate whether any new or expanded preclinical testing, clinical trials, Product Development, or manufacturing of any real or intellectual property resulting from the award can be conducted in this state, including the establishment of facilities to meet this purpose;

(11) An agreement that the Grant Recipient will abide by the Uniform Grant Management Standards (UGMS) adopted by the Governor's Office, if applicable unless one or more standards conflicts with a provision of the Grant Contract, Chapter 102, Texas Health and Safety Code, or the Institute's administrative rules. Such interpretation of the Institute rules and UGMS shall be made by the Institute;

(12) An agreement that the Grant Recipient is under a continuing obligation to notify the Institute of any adverse conditions that materially impact milestones and objectives included in the Grant Contract;

(13) An agreement that the design, conduct, and reporting of the Cancer Research or Prevention project will not be biased by conflicting financial interest of the Grant Recipient or any individuals associated with the Grant Award. This duty is fulfilled by certifying that an appropriate written, enforced Conflict of Interest policy governs the Grant Recipient.

(14) An agreement regarding the amount, schedule, and requirements for payment of Grant Award funds, if such advance payments are approved by the Oversight Committee in accordance with this chapter. Notwithstanding the foregoing, the Institute may require that up to ten percent of the final tranche of funds approved for the Grant Award must be expended on a reimbursement basis. Such reimbursement payment shall not be made until close out documents described in this section and required by the Grant Contract have been submitted and approved by the Institute;

(15) An agreement to provide quarterly Financial Status Reports and supporting documentation for expenses submitted for reimbursement or, if appropriate, to demonstrate how advanced funds were expended;

(16) A statement certifying that, as of June 14, 2013, the Grant Recipient has not made and will not make a contribution, during the term of the Grant Contract, to the Institute or to any foundation established specifically to support the Institute;

(17) A statement specifying the agreed effective date of the Grant Contract and the period in which the Grant Award funds must be spent. If the effective date specified in the Grant Contract is different from the date the Grant Contract is signed by both parties, then the effective date shall control;

(18) A statement providing for reimbursement with Grant Award funds of expenses made prior to the effective date of the Grant Contract at the discretion of the Institute. Pre-contract reimbursement shall be made only in the event that:

(A) The expenses are allowable pursuant to the terms of the Grant Contract;

(B) The request is made in writing by the Grant Recipient and approved by the Chief Executive Officer; and

(C) The expenses to be reimbursed were incurred on or after the date the Grant Award recommendation was approved by the Oversight Committee.

(19) Requirements for closing out the Grant Contract at the termination date, including the submission of a Financial Status Report, a final Grant Progress Report, a equipment inventory, a HUB and Texas Business report, a revenue sharing form, a single audit determination report form and a list of contractual terms that extend beyond the termination date;

(20) A certification of dedicated Matching Funds equal to one-half of the amount of the Research Grant Award that includes the name of the Research Grant Award to which the matching funds are to be dedicated, as specified in Section §703.11 of this chapter (relating to Requirement to Demonstrate Available Funds for Cancer Research Grants);

(21) The project deliverables as described by the Grant Application and stated in the Scope of Work for the Grant Contract reflecting modifications, if any, approved during the Peer Review process or during Grant Contract negotiation; and

(22) An agreement that the Grant Recipient shall notify the Institute and seek approval for a change in effort for any of the Senior Members or Key Personnel of the research or prevention team listed on the Grant Application, including any proposed temporary leave of absence of a Principal Investigator, Program Director, or Company Representative.

(23) An agreement that the Grant Recipient is legally responsible for the integrity of the fiscal and programmatic management of the organization.

(24) An agreement that the Grant Recipient is responsible for the actions of its employees and other research collaborators, including third parties, involved in the project. The Grant Recipient is responsible for enforcing its standards of conduct, taking appropriate action on individual infractions, and, in the case of financial conflict of interest, informing the Institute if the infraction is related to a Grant Award.

(d) The Grant Recipient's failure to comply with the terms and conditions of the Grant Contract may result in termination of the Grant Contract pursuant to the process prescribed in the Grant Contract and trigger repayment of the Grant Award funds.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT: CHIEF OPERATING OFFICER REPORT
DATE: FEBRUARY 8, 2021

CPRIT Financial Overview for FY 2021 Quarter 1

FY 2021, Quarter 1 Operating Budget

CPRIT encumbered or expended 39% of the almost \$4.5 million budgeted in Indirect Administration and 82% of the approximately \$18 million budgeted in Grant Review and Award Operations. The Grant Review and Award Operations budget includes the majority of the agency's vendor contracts, including the \$9.9 million contract for grant management support services with GDIT. The entire contract amounts are encumbered in the accounting system when the contracts are initiated.

CPRIT received \$44,809 in revenue sharing payments during the first quarter and represents the total deposits for the year to date. These payments were deposited in the Cancer Prevention and Research Interest and Sinking Fund 5168. The cumulative total of payments received over the lifetime of the agency now exceeds \$4.7 million.

FY 2021, Quarter 1 Performance Measure Report

CPRIT reported on its two quarterly key performance measures to the Legislative Budget Board. CPRIT did not report any company relocations to the state during the first quarter of 2021. CPRIT came close to achieving almost half (approximately 234,404 people) of the annual 500,000-person served target for the prevention program measure of the number of people served through CPRIT's prevention and control grants.

Debt Issuance History

In January 2021, TPFA issued \$59 million of general obligation commercial paper notes on CPRIT's behalf. This was the second tranche of commercial paper notes issued this fiscal year and supports grant award reimbursements. The remaining \$126.3 million of projected commercial paper notes needed for the year will be issued by June 2021.

FY 2021 Budget Transfer Request to the Legislative Budget Board

On January 11, 2021, CPRIT was notified along with other state agencies of the agency's FY 2020 Statewide Cost Allocation Plan (SWCAP) of the agency's share of the state's central administrative costs used by most state agencies. Example of these services include accounting services, accounting systems, and procurement services provided by the Comptroller's Office of Public Accounts and tenancy in a state building managed by the Texas Facilities Commission.

The amount of CPRIT's FY 2020 cost share to be reimbursed to the state treasury is \$448,525 by the end of FY 2021. This compares to a \$68,844 cost share reimbursement charged to CPRIT for FY 2019. That makes the \$448,525 cost share charge a 552% increase over the prior year. After performing an evaluation of the agency's current operating budget including other unanticipated expenses such as the search firm services for a new Chief Scientific Officer, I have determined that the agency cannot absorb the almost \$450,000 SWCAP share. Therefore, Wayne Roberts intends to request authorization from the Legislative Budget Board for a budget transfer of \$448,525 from the research awards budget line item to the indirect administration budget line item under the authority of Rider 4 in the General Appropriations unless the Oversight Committee raises objections to such a request.

The origination of the SWCAP calculation was the identification of a state's central services fixed costs and a state's capability to recover those costs from federally funded programs based on a documented calculation methodology. The cost allocation analysis and methodology must conform to federal law and be certified by a state official. The responsibility for the annual SWCAP analysis belongs to the Office of the Governor which contracted with MGT of America Consulting, LLC to prepare the FY 2020 SWCAP.

The SWCAP calculation for a given year, in this case FY 2020, is based on actual state expenditures and the allocation data incurred by the state's central service agencies from two years prior, in this case FY 2018. While the original purpose was the recovery of federal funds for central services, the SWCAP costs in Texas are also recovered from any agency with a non-general revenue funding source such as CPRIT's general obligation bond proceeds. With the FY 2020 SWCAP charge being based on the expenses and use of central services in FY 2018 when CPRIT first began actively using the CPA-provided CAPPs financial modules for all of its accounting and procurement processes, I foresee that CPRIT's SWCAP charge will remain at this level in future years.

Cancer Prevention and Research Institute of Texas
Quarterly Financial Report
As of November 30, 2020

Indirect Administration (B.1.1.)

	2021 Appropriated	2021 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001 Salaries and Wages	\$ 1,787,425	\$ 1,787,425		\$ 346,179	1,441,246	19%	\$ 346,179	\$ 1,441,246
1002 Other Personnel Costs	38,785	38,785		4,533	34,252	12%	4,533	34,252
2001 Professional Fees and Services	1,808,662	1,900,943		1,028,333	872,610	54%	1,028,333	872,610
2003 Consumable Supplies	24,000	24,000		879	23,121	4%	879	23,121
2004 Utilities	58,600	58,600		36,102	22,498	62%	36,102	22,498
2005 Travel	45,000	45,000		-	45,000	0%	-	45,000
2006 Rent-Building	11,000	11,000		2,601	8,399	0%	2,601	8,399
2007 Rent-Machine and Other	32,172	32,172		26,000	6,172	81%	26,000	6,172
2009 Other Operating Expenses	554,409	574,409		298,342	276,067	52%	298,342	276,067
Subtotal - Indirect Administration (B.1.1.)	\$ 4,360,053	\$ 4,472,334	1.49%	\$ 1,742,969	\$ 2,729,365	39%	\$ 1,742,969	\$ 2,729,365

Grant Review and Award Operations (A.1.3.)

	2021 Appropriated	2021 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001 Salaries and Wages	\$ 2,993,084	2,993,084		\$ 815,485	\$ 2,177,599	27%	\$ 815,485	\$ 2,177,599
1002 Other Personnel Costs	45,000	45,000		9,046	35,954	0%	9,046	35,954
2001 Professional Fees and Services	9,436,363	14,801,470		13,879,785	921,685	94%	13,879,785	921,685
2003 Consumable Supplies	-	-		-	-	0%	-	-
2004 Utilities	12,000	12,000		889	11,111	7%	889	11,111
2005 Travel	65,000	45,000		-	45,000	0%	-	45,000
2009 Other Operating Expenses	355,283	131,567		7,442	124,125	6%	7,442	124,125
Subtotal - Grant Operations (A.1.3.)	\$ 12,906,730	\$ 18,028,121	6.02%	\$ 14,712,647	\$ 3,315,473	82%	\$ 14,712,647	\$ 3,315,473

Grants

	2021 Appropriated	2021 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
4000 Grants - Prevention (A.1.2)	\$ 28,050,081	\$ 28,080,479		\$ -	\$ 28,080,479	0%	\$ -	\$ 28,080,479
4000 Grants - Research (A.1.1.)	251,620,104	\$ 249,135,528		-	\$ 249,135,528	0%	-	249,135,528
Subtotal - Grants	\$ 279,670,185	\$ 277,216,007	92.49%	\$ -	\$ 277,216,007	0%	\$ -	\$ 277,216,007
Grand Totals	\$ 296,936,968	\$ 299,716,462	100.00%	\$ 16,455,616	\$ 283,260,846	5%	\$ 16,455,616	\$ 283,260,846

**Cancer Prevention and Research Institute of Texas
Cancer Prevention and Research Institute Fund Account - 5136
As of November 30, 2020**

	11/01/2020- 11/31/2020	AY 21 Year to Date as of 11/30/2020
Beginning Balance : 9/01/2020		\$ 600,506
Increases:		
(1)	\$ -	\$ -
(2)	-	
Total Increases	\$ -	\$ 600,506.00
Reductions:		
Expenditures - Appropriated	\$ -	\$ -
	\$ -	\$ -
	\$ -	\$ -
Total Reductions	\$ -	\$ -
Ending Balance, 11/30/2020		\$ 600,506.00

Note: (1) The Institute received a settlement from the Texas Cancer Coalition (TCC). This amount represents the final distribution and transfer of all funds (\$303,877) from the TCC which ceased operations in May 2013. These funds are in the State Treasury but are not appropriated to CPRIT. The beginning balance reflects the transfer of all TCC funds.

**Cancer Prevention and Research Institute of Texas
License Plate Trust Fund Account - 0802
As of November 30, 2020**

	11/01/2020- 11/31/2020	AY 21 Year to Date as of 11/30/2020
Beginning Balance : 9/01/2020		\$ 30,397.95
Increases:		
(1) License Plate Revenue Received	\$ 496.82	\$ 1,803.92
Total Increases	\$ 496.82	\$ 32,201.87
Reductions:		
Expenditures - Appropriated	\$ -	\$ -
	-	-
Total Reductions	\$ -	\$ -
Ending Balance, 11/30/2020		\$ 32,201.87

Note:

Balance forward from 2020 License Plate \$30,397.95

Cancer Prevention and Research Institute of Texas

Appropriated Receipts - 666

As of November 30, 2020

	<u>11/01/2020- 11/31/2020</u>	<u>AY 21 Year to Date as of 11/30/2020</u>
<u>Beginning Balance : 9/01/2020</u>		\$ 83,996.90
Increases:		
(1) Product Development Application Fees Received	\$ -	\$ -
(2) Appropriated Receipts applied to payments	\$ -	\$ -
(3) Conference Registration Fees	\$ -	\$ -
(4) Conference Registration Fees-Credit Card	\$ -	\$ -
Total Increases	<u>\$ -</u>	<u>\$ -</u>
Reductions:		
Conference Expenditures - Appropriated	\$ -	\$ -
Credit Card Fees Expended	\$ -	\$ -
Refund-Application Fees	\$ -	\$ -
Legal Services Expenses (Application Fees)	\$ -	\$ -
Total Reductions	<u>\$ -</u>	<u>\$ -</u>
<u>Ending Balance, 11/30/2020</u>		<u><u>\$ 83,996.90</u></u>

Forward balance for FY 2020 is \$83,896.90
 Application Fees + \$100 Donation

Cancer Prevention and Research Institute of Texas
Interest & Sinking Fund Account - 5168
As of November 30, 2020

	11/01/2020- 11/31/2020	AY 21 Year to Date as of 11/30/2020
Beginning Balance : 9/01/2020		\$ 2,237,500.68
Increases:		
(1) Revenue Sharing / Royalties	\$ 44,809.39	\$ 44,809.39
Total Increases	\$ 44,809.39	\$ 2,282,310.07
Reductions:		
Expenditures - Appropriated	\$ -	\$ -
	\$ -	-
	\$ -	-
Total Reductions	\$ -	\$ -
Ending Balance, 11/30/2020		\$ 2,282,310.07

Balance forward from FY 2019 is \$2,237,500.68

**Cancer Prevention and Research Institute of Texas
FY 2021, Quarter 1 Performance Measure Report**

Measure	Targeted Performance	QTR 1	QTR 2	QTR 3	QTR 4	Sum of QTRs	% of Mandate Attained
Number of People Served by Institute Funded Prevention and Control Activities	500,000	234,404	0	0	0	234,404	46.88%
Number of Entities Relocating to TX for Cancer Research Related Projects	1	0	0	0	0	0	0.00%
Annual Age-adjusted Cancer Mortality Rate	145.2	N/A	N/A	N/A	N/A	0	0.00%
Number of Published Articles on CPRIT-Funded Research Projects	1,000	N/A	N/A	N/A	N/A	0	0.00%
Number of New Jobs Created and Maintained	1,500	N/A	N/A	N/A	N/A	0	0.00%

Variance Explanations

Number of People Served by Institute Funded Prevention and Control Activities

CPRIT prevention grantees have been successful at delivering cancer prevention education and clinical services to more people than they anticipated, stretching their CPRIT-grant funds further to serve Texans. During the COVID-19 pandemic, they found alternative means through the use of remote technologies such as the telephone, electronic messages, and videoconferencing, to continue delivering cancer prevention education to Texans. They have also resumed providing cancer prevention clinical services, such as mammograms and colonoscopies, following COVID-19 precautions which include the use of COVID-19 tests and a greater amount of PPE.

Number of Entities Relocating to TX for Cancer Research Related Projects

This output is dependent on the number of companies applying for CPRIT Company Awards that can successfully advance through CPRIT's rigorous review and evaluation process, receive an award and actually relocate operations to Texas. Therefore, the results vary. A company must meet 4 of CPRIT's 7 criteria for a relocation to be considered complete.

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2010	\$ 225,000,000	September 9, 2009	\$ 9,100,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2010		September 9, 2009	\$ 3,600,000		Commercial Paper Notes	Series B, Tax-Exempt	Defeased with cash July 2011	
2010		March 12, 2010	\$ 63,800,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2010		August 26, 2010	\$ 148,500,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				\$ 225,000,000				
2011	\$ 225,000,000	September 7, 2010	\$ 11,800,000		Commercial Paper Notes	Series A, Taxable		
2011		August 10, 2011	\$ 51,000,000		G.O. Bonds	Taxable Series 2011	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
2011		August 10, 2011	\$ 232,045,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2011	Par amount of refunding; Refunded \$233.2M of GOCP CPRIT Series A (9/9/09, 3/12/09, 8/26/09, 9/7/10)	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
				\$ 62,800,000				
2012	\$ 300,000,000	September 7, 2011	\$ 3,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		December 8, 2011	\$ 3,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		March 2, 2012	\$ 12,300,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		June 21, 2012	\$ 15,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		August 16, 2012	\$ 42,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				\$ 75,700,000				
2013	\$ 300,000,000	September 6, 2012	\$ 9,600,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2013		May 16, 2013	\$ 13,400,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				\$ 23,000,000				
2014	\$ 300,000,000	November 25, 2013	\$ 55,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2014		March 13, 2014	\$ 47,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2014		June 17, 2014	\$ 60,300,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2014		July 8, 2014	\$ 233,280,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2014	Par amount of refunding; Refunded \$237.88M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.327184%
				\$ 162,500,000				
2015	\$ 300,000,000	November 5, 2014	\$ 57,600,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2015		April 29, 2014	\$ 112,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2015		June 26, 2015	\$ 75,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				\$ 244,600,000				

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2016	\$ 300,000,000	September 22, 2015	\$ 55,400,000		Commercial Paper Notes	Series A, Taxable		
2016		October 29, 2015	\$ 300,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2015C	Par amount of refunding; Refunded \$300M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		October 29, 2015	\$ 69,800,000		G.O. Bonds	Taxable Series 2015C	Par amount of new money; Disbursed to CPRIT January 2016	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		May 16, 2016	\$ 92,100,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2016		August 29, 2016	\$ 60,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				\$ 277,300,000				
2017	\$300,000,000	October 19, 2016	\$ 58,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2017		January 5, 2017	\$ 58,900,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2017		February 8, 2017	\$ 269,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2017	Par amount of refunding; Refunded \$269M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.4622%
2017		February 8, 2017	\$ 106,000,000		G.O. Bonds	Taxable Series 2017	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 3.4622 %
				\$ 222,900,000				
2018	\$300,000,000	September 29, 2017	\$ 68,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2018		March 8, 2018	\$ 99,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2018		July 11, 2018	\$ 55,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				\$ 222,200,000				
2019		September 21, 2018	\$ 222,200,000		G.O. Bond (Refunding Bonds)	Taxable Series 2018	Par amount of refunding; Refunded \$222.2M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.720632%
2019	\$300,000,000	September 21, 2018	\$ 75,975,000		G.O. Bonds	Taxable Series 2018	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 3.720544%
2019		March 28, 2019	\$ 77,725,000		Commercial Paper Notes	Series A, Taxable		Interest rates between 1.90% - 2.55%
2019		July 12, 2019	\$ 54,000,000		Commercial Paper Notes	Series A, Taxable		Interest rates between 1.95% - 2.35%
				\$ 207,700,000				

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2020		September 16, 2019	\$ 64,300,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 2.10%
2020		January 9, 2020	\$ 52,000,000		Commercial Paper Notes	Series A, Taxable		
2020		April 23, 2020	\$ 248,025,000		G.O. Bond (Refunding Bonds)	Taxable Series 2018	Par amount of refunding: Refunded \$243.025M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 2.644360%
2020		April 23, 2020	\$ 115,000,000		G.O. Bonds	Taxable Series 2018	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 2.644360%
				\$ 231,300,000				
2021	\$300,000,000	September 11, 2020	\$ 75,000,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 0.23% for 90 days
		January 14, 2021	\$ 59,000,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 0.23% for 118 days
				\$ 134,000,000				
TOTAL ISSUED TO DATE				\$ 2,089,000,000				



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To: OVERSIGHT COMMITTEE MEMBERS
From: HEIDI MCCONNELL, CHIEF OPERATING OFFICER
Subject: FY 2021 SEARCH FIRM SERVICES
Date: PROCUREMENT FEBRUARY 15, 2021

Recommendation

CPRIT staff recommends that the Oversight Committee approve a proposed search firm contract with Spencer Stuart for an amount not to exceed \$175,000. The contract authorizes additional out of pocket expenses, such as travel, but only to the extent that CPRIT pre-approves the costs. Payment is based upon delivery of services, including conducting a national search for CPRIT's next Chief Scientific Officer (CSO) and facilitating the CSO interview process.

Discussion

CPRIT CSO Dr. Jim Willson notified CPRIT that he intends to leave the agency this summer. As is our standard process when hiring a new CSO, CPRIT will use a professional search firm to conduct the national search for qualified candidates, evaluate applications, prepare comprehensive candidate profiles for the interview committee, and facilitate interviews. CPRIT is not engaging the search firm to act as a consultant because the firm will not advise the CPRIT's CEO on the choice of a CSO.

We received three proposals in response to the request seeking competitive bids. CPRIT staff evaluated the proposals and identified a preferred vendor. We recommend that CPRIT execute a contract with Spencer Stuart at a not-to-exceed amount of \$175,000, exclusive of pre-approved out of pocket expenses. Spencer Stuart is an international executive search firm that has extensive experience in recruiting executives to academic research universities and life sciences institutions. CPRIT has a long history with Spencer Stuart; they have assisted CPRIT in every CSO search we have conducted since the outset of the agency.

We believe that the recommended contract represents the best value to the agency for the quality of services and depth of experience available in this specialized area. The Oversight Committee must consider and approve any contract exceeding \$100,000 before CPRIT may execute the contract. CPRIT staff discussed the search firm contract solicitation and proposal review process with the Audit Subcommittee. However, we had not yet completed the contract negotiations by the February 8 Audit Subcommittee meeting, so the subcommittee does not have a recommendation regarding the Spencer Stuart contract.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: CHRIS CUTRONE, SENIOR COMMUNICATIONS SPECIALIST
SUBJECT: COMMUNICATIONS UPDATE
DATE: FEBRUARY 8, 2021

The following is an overview of the agency’s communication activities from November 2020 to February 2021.

Earned Media

Coverage:

- 3 articles featured CPRIT
- 57 additional articles mentioned CPRIT (stories primarily focused on work of grantees)

Coverage Highlights: (see clipped articles following report)

- November 19, 2020: *“Houston expert: Houston should focus on developing the region's life sciences sector” - Innovation Map*
- November 19, 2020: *“El Paso prepares to distribute upcoming COVID-19 vaccine”- KFOX 14 El Paso*
- December 1, 2020: *The Scientist Magazine - “Gloria Echeverria Investigates an Insidious Form of Breast Cancer”*
- January 13, 2021: *Austin American Statesman - “Texas lawmaker proposes \$3 billion plan to fight future pandemics”*
- January 19, 2021: *“New imaging equipment aids TTUHSC’s cancer research”- KAMR NBC 4/KCIT Fox 14 (Nexstar) Amarillo*
- January 21, 2021: *“Houston biotech startup raises millions to battle pediatric cancer”- Innovation Map*
- January 24, 2021: *“Our view: State must be better prepared for next pandemic” – Amarillo Globe-News*
- January 27, 2021: *“DoD Awards Funding to Pulmotect to Study Repurposed PUL-042 Against COVID-19”- Global Biodefense*
- February 5, 2022: *“TMC cancer therapeutic accelerator names inaugural cohort” – Innovation Map*

Outreach

On December 8, 2020, Brazos Valley Economic Development Corporation, with assistance from Communications, held a webinar event on CPRIT funding opportunities and showcased CPRIT grantees and stakeholders. Participants included research grantees and stakeholders from the Texas A&M System as well as Fujifilm Diosynth.

To view a recording of the event, please click on the following link: <https://cprit.us/37ThNC9> (Passcode: b=pAfh^8)

Digital Media

Communications and IT staff are in the final stages of testing the CPRIT Scholar application. This online tool will allow the scholars or their institutions to update their own profiles on our website at <https://scholars.cprit.texas.gov/>. We will work with communications counterparts at the institutions for training and support when CPRIT deploys the application.

Social Media

Communications is showcasing the 2020 Annual Report via social media, running on a post a day for most of the month of February. World Cancer Day on February 4th saw some great engagement with our post about CPRIT's recognition as a Gold Standard Health Champion. Also, many of our grantee institutions did social media and tagged us on World Cancer Day.

Social media content during November was inspired by it being Lung Cancer Awareness Month and Pancreatic Cancer Awareness Month with November 19th being World Pancreatic Cancer Day. January was Cervical Cancer Awareness Month, and we produced a video shared on social media featuring CPRIT grantee Abbey Berenson of UTMB discussing cervical cancer and HPV prevention. The video can be viewed here on our YouTube page: <https://www.youtube.com/watch?v=2HG4d3lOLwg>

Social media statistics for the past month are below.

Twitter (January 12, 2021-February 8, 2021):

- Total Tweets: 18
- Tweet Impressions: 18.9K
- Profile Visits: 997
- Mentions: 30
- New Followers: 34 (2,750 total)
- Top tweet: CPRIT announces the release of five RFAs for the Academic Research program. Complete RFAs and instructions detailing applicable deadlines and requirements are available on the Apply for Funding page of CPRIT's website: <http://cprit.us/2Wn7m1y>
- Impressions: 2,380 people
Engagements: 84

LinkedIn (January 8, 2021-February 7, 2021):

- Total Updates: 12
 - Reactions: 85
 - Page views: 140
 - Unique Visitors: 61
 - New followers: 30 (1,132 total)
 - Top Update: CPRIT grantee [Pulmotect, Inc.](#) has been awarded \$6M from the [United States Department of Defense](#) to complete two ongoing [#COVID-19](#) Phase-2 clinical trials of its innate immune-stimulating drug PUL-042. CPRIT funded Pulmotect's development of the PUL-042 drug, which harnesses the power of the innate immune system - the front line of disease defense - to fight off a wide range of respiratory infections. Initially targeting respiratory complications caused by cancer treatments, preclinical studies of PUL-042 have shown compelling protection against a broad range of respiratory pathogens including the coronaviruses that cause MERS and SARs. Read the [InnovationMap](#) story here: <http://cprit.us/3pxc10m>
- Impressions: 459 people
Clicks: 22
Reactions: 19
Engagement rate: 10.24%

Facebook (January 11, 2021-February 7, 2021):

- Total posts: 17
 - Reach: 1.5K users
 - Engagement: 339 reactions/clicks
 - Page Views: 149
 - Top Post: Check out this feature from [KVIA ABC-7](#) on [Tiempo de Vacunarte](#), a CPRIT-supported [Texas Tech University Health Sciences Center El Paso #HPV](#) vaccination program active in the border counties of El Paso, Hudspeth, Culberson, Presidio and Brewster.
[#cervicalcancerawarenessmonth](https://cprit.us/2M9m11i)
- Post Reach: 145 users
Engagement: 6 clicks, 228 reactions



GUEST COLUMN

Houston expert: Houston should focus on developing the region's life sciences sector



Steven Scarborough Nov 19, 2020, 11:04 am

GUEST COLUMN



Houston needs to work on developing its life sciences infrastructure, like what the TMC3 project is providing. *Courtesy of Elkus Manfredi Architects*

The region's health care sector has been Greater Houston's job growth engine over the past few decades – creating new jobs at a rate 75 percent greater than the overall economy – according to research published last month in Center for Houston's Future report, *Houston's Economic Future: Health Care*.

But data from the Bureau of Economic Analysis and Bureau of Labor suggest that in many ways the economic footprint of our health care sector is not in line with the share of employment that health care commands across the region: While health care accounts for about 12 percent of the region's jobs, it is responsible for just 5.4 percent of Greater Houston's total gross domestic product.

By comparison, our energy sector holds roughly the same share of GDP as health care, but employs about just a fifth the number of employees.

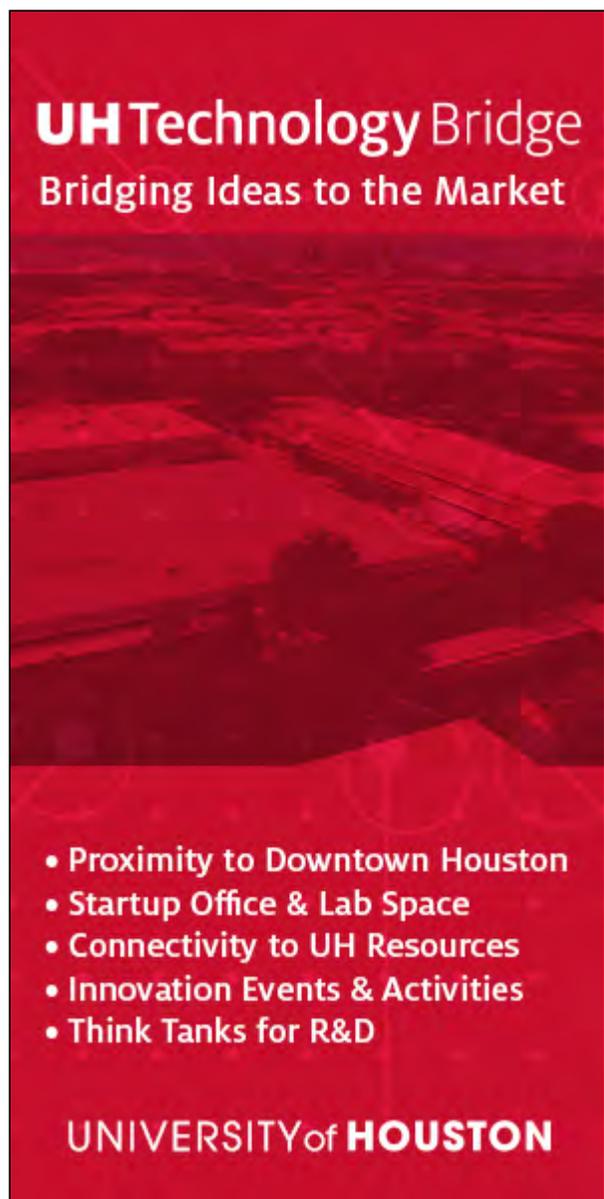
To bridge this gap, Houston should focus on developing the region's life sciences sector, a promising economic development area with a potentially high economic payoff.

The life sciences represent a trillion-dollar plus global industry spanning pharmaceutical development, medical device manufacturing, research and commercialization of biotechnology and more. The employment multiplier – a measure of the economic contribution an occupation has on the greater economy – of a life sciences job exceeds that of generic jobs in health care by 40 percent.

Modeling conducted by the Center suggests a concerted effort to develop the region's life sciences industries compared to a 'business as usual' approach would yield an additional \$13.1 billion in GDP and 73,000 jobs by 2036.

Historically, this industry has clustered on the East and West Coasts of the U.S., but recent efforts signal encouraging signs of progress.

Examples include the creation of TMC3 at the Texas Medical Center, a collaborative, multi-institution



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effort to build a life sciences research campus; the development of Houston's innovation corridor anchored by The Ion; and investment from the Cancer Prevention & Research Institute of Texas (CPRIT), a \$6 billion state program to advance cancer research efforts and promote economic development.

Greater Houston has the potential to become the so-called Third Coast if we build on momentum that's starting to take hold.



Findings from our report suggest, however, that more work is needed to advance the life sciences.

This sector continues to grow rapidly—employment in this area rose by 37 percent from 2009 to 2019. Yet, the Center identified troubling data points, including that the number of people working in biotechnology and life sciences research and development declined by 13 percent from 2018 to 2008.

Our research identified several hurdles the region still faces in cultivating our still-nascent life sciences industry. First, Houston is still energy-dominant, with limited investment capital glowing to the life sciences. We must figure out how to attract venture capital, whether it be from Boston, Silicon

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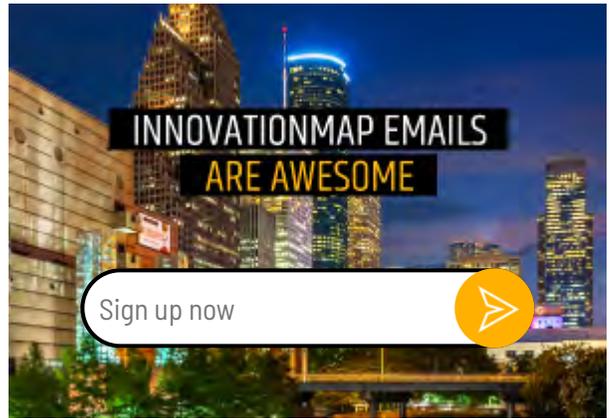
13-6

Valley or elsewhere, to facilitate the growth of our existing biotechnology and life sciences firms and boost the rate of startup formation.

Second, Greater Houston continues to struggle with retaining life sciences talent, businesses and intellectual property. In some of the roughly 50 interviews the Center conducted with health care subject-matter experts, we heard that some businesses in the field relocate from Texas as soon as they begin growing. We believe the region should consider developing a cross-sector push for innovation that includes effectively scaling the research catalyzed by CPRIT.

By adopting a common vision and working together to grow Greater Houston's life sciences cluster, we can boost our economy and better position our health care sector to capitalize on the myriad new health care technologies that will emerge over the next couple decades.

Steven Scarborough is manager of strategic initiatives at Center for Houston's Future and the principal author of Houston's Economic Future: Health Care.



El Paso prepares to distribute upcoming COVID-19 vaccine

by David Cross | Jala Washington

Thursday, November 19th, 2020

EL PASO, Texas (KFOX14) — Officials with the city of El Paso spoke Thursday during a news conference to provide details on distributing an upcoming COVID-19 vaccine and how contact tracing efforts are leading to more focused mitigation responses in the community.

“I’m actually pretty hopeful today,” El Paso Mayor Dee Margo said to start the news conference as he broke down the latest data from contact tracing efforts in El Paso.

Margo said contact tracing efforts have identified the areas of COVID-19 spread that need to be addressed and officials can now target those with mitigation efforts alongside the continuation of existing public health ordinances.

According to Margo, El Paso will have seven sites for storing the Pfizer COVID-19 vaccine, which Texas Gov. Greg Abbott said Thursday officials expect to be available by the end of December.

El Paso has the resources and equipment in health care to handle the current COVID-19 situation, Margo said.

Margo said he is more concerned that El Pasoans are not taking care of their health outside of the pandemic, noting a drop in cancer screenings in the region.

He revealed shocking numbers that show just how many people are putting their overall healthcare off.

“We are a very caring community about each other, and we need to continue that as we go forward in this pandemic,” Margo said.

"We are fine on our healthcare and supplies," Margo said. "Now, what I am concerned about is people failing to take care of themselves in other medical areas."

Margo said he serves on the Cancer Prevention and Research Institute of Texas, representing El Paso, where he learned Wednesday there's a major problem right now in our region.

"If you look at the month's March to May, a year ago, we did 978 colorectal cancer screenings. This year we've only done 290," Margo said.

According to Margo, there were 56 colorectal cancer diagnostics last year, compared to just 14 this year. And he said breast cancer screenings are down from 303 to 42. A lack of cervical screenings is alarming for Margo too.

"My biggest concern, I'll just say, on cervical screenings, we did 181 from March to May last year," Margo said. "We've done 32 this year."

Margo worries people could be putting themselves more at risk urging everyone to take their well-being seriously.

"We've got to maintain our health," Margo said. "And we can't let other things, and this pandemic dictate that. It is imperative."

It's important to remember, with cancer--early detection is key.

Margo said that although a vaccine is on the way, it is important that the community continues to protect themselves from COVID-19 by following public health guidelines.

"It is prudent to say, we still have a dire situation in El Paso," City-County Health Authority Dr. Hector Ocaranza said.

Ocaranza thanked community members who are taking precautions against COVID-19 and following local health orders.

"I strongly recommend, strongly recommend, that people do not do large gatherings," Ocaranza said in regard to the upcoming Thanksgiving holiday.

El Paso Public Health Director Angela Mora broke down preparations to distribute a COVID-19 vaccine and said local health officials have been in contact with Pfizer on distribution plans.

According to Mora, there are 139 local providers enrolled in the vaccine distribution program in El Paso.

"We're going to have a large capacity to immunize the El Paso community," said Mora.

According to Mora, one person administering vaccines will be able to vaccinate more than 40 people a day, and with 139 local facilities providing vaccines, El Paso is ready to distribute it in large numbers.

The El Paso Department of Public Health reported 672 new COVID-19 cases and 19 additional deaths related to the disease on Thursday.

According to health officials, there have now been a total of 77,977 confirmed COVID-19 cases in El Paso, 41,941 of which have recovered, and 823 people have died from the diseases caused by the novel coronavirus.

<https://kfoxtv.com/news/coronavirus/el-paso-officials-to-update-community-on-covid-19-in-region>

Gloria Echeverria Investigates an Insidious Form of Breast Cancer

The newly minted Baylor College of Medicine faculty member is working to crack the mystery of triple negative breast cancer.



Max Kozlov

Dec 1, 2020

As a little girl, Gloria Echeverria didn't want to be the president or a firefighter. Instead, she promised her mother that she would one day run the US Centers for Disease Control and Prevention. Her grade-school teachers encouraged her interest in science, Echeverria tells *The Scientist*.

"Perhaps it subconsciously played some kind of role, seeing these awesome women who were so knowledgeable and passionate about the subject."

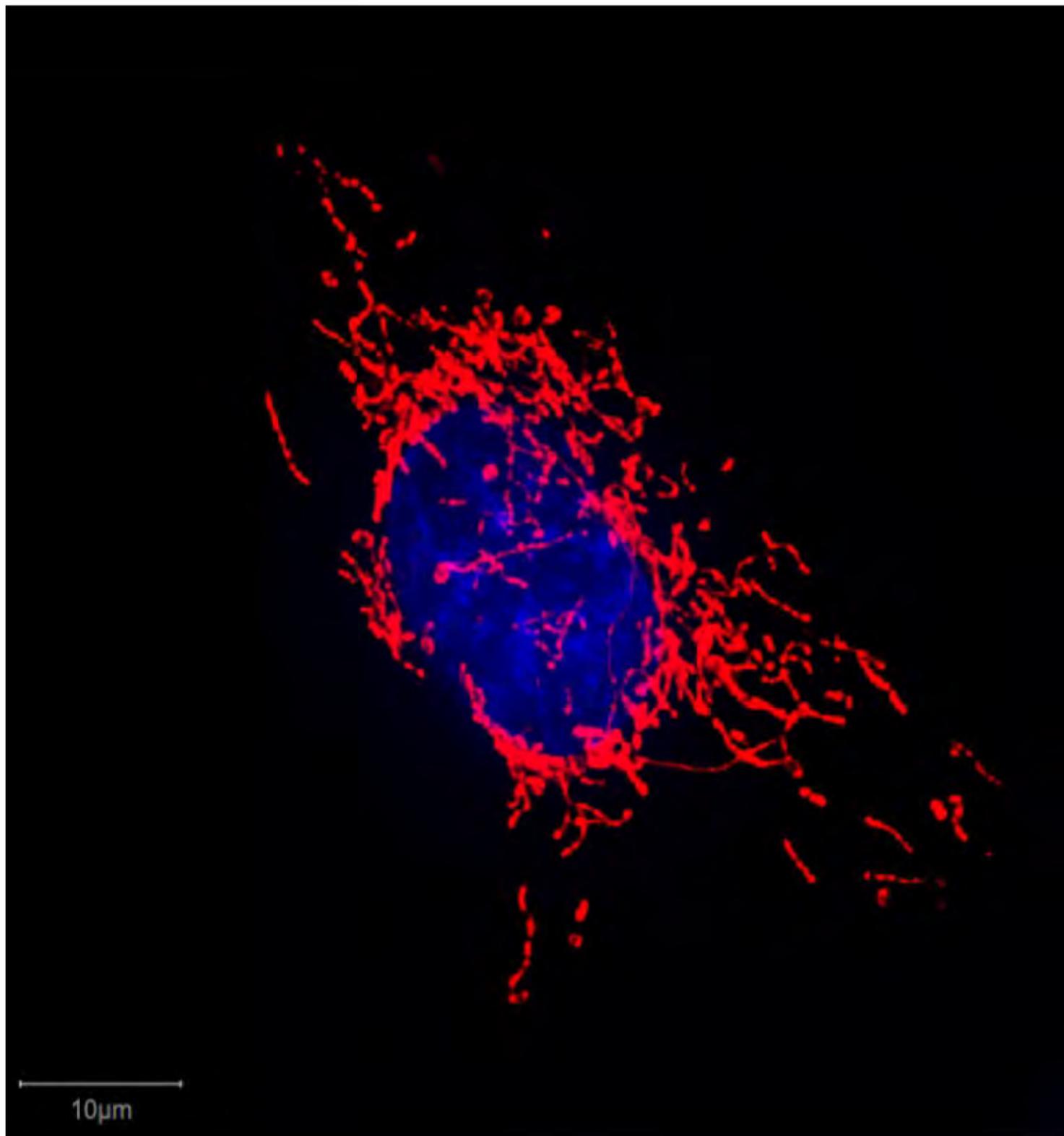
Echeverria enrolled at Texas A&M University in 2004 with her sights set on a scientific research career. By her sophomore year, she was investigating how [beneficial fungal organisms that grow on the roots of plants can be genetically enhanced](#) to protect crops from pathogens. While wrapping up her undergraduate training in biochemistry and genetics, Echeverria began to apply for PhD programs, and she had a new focus—biomedical science. "I really wanted to take that knowledge from the plant pathology lab, and I wanted to apply it to something that I thought might have a nearer-term impact on human health and well-being," she says.

In 2008, she joined Thomas Cooper's lab at Baylor College of Medicine in Houston and studied [how RNA splicing can go haywire](#) in patients with the genetic mutation that causes the muscular disease myotonic dystrophy type 1. After completing her PhD in 2013, Echeverria moved across town to Helen Piwnica-Worms's lab at MD Anderson Cancer Center to study another disease she'd heard about in her graduate studies, triple negative breast cancer (TNBC).

[Up to 15 percent of all breast cancers](#) are TBNCs. Scientists gave the cancer that name because the malignant cells don't have estrogen or progesterone receptors and don't overexpress the [HER2](#) protein; all three are therapeutic targets in breast cancer. TNBC is particularly hard to treat because it is "defined by what it lacks, not by what it is," Echeverria says. "One of the big challenges with triple negative is it's very heterogeneous," meaning that each tumor can have different types of malignant cells within it and that no two individuals' TNBCs are the same, she explains. "It's kind of like the leftover bucket for all the cancers that don't have the things that we understand well."

To determine how [TNBC's high heterogeneity contributes to metastasis](#), Echeverria, Piwnica-Worms, and their colleagues inserted distinct genetic labels called DNA barcodes into the different malignant cell types of patient-derived cancer samples, and then transplanted the cells into the mammary glands of mice. Using the barcodes to track how the cancer cells spread, Echeverria identified a subset that effectively metastasized and colonized other organs. "What sets great trainees apart from others are those who are fearless and willing to embrace new technologies [such as DNA barcoding] to answer key questions," Piwnica-Worms says, and Echeverria is not only

ABOVE: Gloria Echeverria
AGAPITO SANCHEZ JR., BAYLOR COLLEGE OF
MEDICINE



Fluorescent microscopy image of the network of mitochondria (red) in triple negative breast cancer (nucleus stained in blue)
MOKRYUN (LILY) BAEK, BAYLOR COLLEGE OF MEDICINE

fearless but has a “great intellect.”

Using the same barcoding method, Echeverria next tested the cancer cells’ [responses to chemotherapy](#) and found that the mice’s tumors “got so small it got hard to measure them,” she says. But once the team halted the treatment the tumors’ growth started skyrocketing again. “We found that we could give tons and tons of chemotherapy over and over again, and we could never prevent them from regrowing,” says Echeverria. 13-11

She and her colleagues published the results in 2019, detailing how the leftover tumors survived the chemo treatment. The cancer cells entered a defensive state, the team found, in which the cells' metabolism shifted to oxidative phosphorylation rather than glycolysis, providing them with an abnormally high amount of energy. An oxidative phosphorylation inhibitor delayed regrowth of the tumors, the team found. The inhibitor is in [Phase 1 clinical trials](#).

Echeverria started her own lab at the Baylor College of Medicine in January, and with the help of a [\\$2 million Fir Time, Tenure-Track Faculty Member Award](#) from the Cancer Prevention and Research Institute of Texas, she will continue her study of TNBC metastasis and the cancer's resistance to treatment. "She's been working her whole life to get to this point now to be an independent PI [principal investigator] and run her own program," says Piwnicka-Worms. "She picked a really important problem and a really important area to investigate, [cancer] metabolism."

Echeverria's research carries personal significance too. Her husband, a radiation oncologist at Baylor, lost his mother to breast cancer when he was 11 years old. Based on what her husband has told her, Echeverria says she suspects that illness might be recognized today as TNBC. "It's really gratifying to me and it really helps drive my work to know that I'm working on something that is a huge need and might one day help someone."

Keywords:

breast cancer, cancer, cell & molecular biology, chemotherapy, disease & medicine, DNA, DNA barcoding, fungus, pathogens, phosphorylation, Scientist to watch, triple receptor-negative breast tumors

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BUSINESS

Texas lawmaker proposes \$3 billion plan to fight future pandemics

Bob Sechler Austin American-Statesman

Published 12:05 p.m. CT Jan. 13, 2021 | Updated 5:08 p.m. CT Jan. 17, 2021

With the coronavirus pandemic still raging nationwide, at least one Texas lawmaker is advocating a leading role for the state in trying to head off such public health calamities in the future.

State Sen. José Menéndez, D-San Antonio, has proposed creating a state agency – funded with up to \$3 billion in taxpayer-backed bonds over 10 years – to provide grants for research into emerging infectious diseases and development of vaccines and other treatments for them.

The new agency would be modeled after the state's cancer-fighting agency, the Cancer Prevention and Research Institute of Texas, commonly known as CPRIT. In 2007, Texas voters initially approved the issuance of \$3 billion in bonds, in increments of up to \$300 million a year, to fund CPRIT grants, and they renewed the effort in 2019 by authorizing an additional \$3 billion.

"Texas likes to pride itself in being forward-thinking and being a leader, so let's be a leader in response to any global pandemic or virus," Menéndez said. "If we could have short-circuited this pandemic, how many lives would we have saved and how many fewer Texans would have died?"

His proposal – detailed in Senate Bill 264, which he filed in advance of the state legislative session that began this week – would create an agency called the Texas Research Consortium to Cure Infectious Diseases, or TRANSCEND for short, based loosely on its initials. As with CPRIT, issuing bonds to pay for the agency's grants would require voter approval.

In addition to helping accelerate research overall, Menéndez said the effort potentially would provide Texans with first dibs on newly developed treatments, because it would enable the

13-13

state to take ownership stakes in entities that receive the grants.

A spokesman for Gov. Greg Abbott didn't respond to an American-Statesman request for comment. But Menéndez said he has been in contact with Abbott's office about the plan, and he characterized the governor as interested in it.

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Larry Schlesinger, president of the nonprofit Texas Biomedical Research Institute, said the proposed new agency would be a "game changer" for Texas because of its potential impact on the overall pace of research into infectious diseases, as well as on the life sciences industry in the state.

Schlesinger, whose San Antonio-based organization has been involved in development of COVID-19 treatments and vaccines, had a hand in helping Menéndez shape SB 264, and he also said he has spoken to Abbott about the broad idea.

"Infectious disease threats are increasing – it is not an 'if' but a 'when' situation" in terms of the emergence of another new deadly virus, he said.

But "at the current time, we have been a reactive society to infectious disease threats," Schlesinger said. The proposed state agency would help change that, he said, representing "an unprecedented opportunity for the state of Texas to be the epicenter for infectious disease research and development to avert pandemics in the future," similar to CPRIT's prominence in fighting cancer.

CPRIT – which has made Texas the nation's second-largest source of public money for cancer research behind only the federal government – is credited with fostering multitudes of promising treatments and with attracting researchers and biomedical companies to the state.

But the price tag to Texas taxpayers hasn't been cheap. State officials estimated in 2019 that the issuance of new CPRIT bonds would cost the state's general fund about \$246 million combined from 2020 through 2024, a figure that doesn't include debt service on previously issued CPRIT bonds.

Such numbers could make creation of a similar taxpayer-funded agency aimed at fighting infectious diseases a hard sell during the 2021 legislative session, when government coffers have been drained by the economic fallout from the current pandemic.

"This may not be a time the state needs to be expanding (its financial commitments) even though this is a noble and very worthy cause," said Justin Yancy, president of the Texas

Business Leadership Council. "I just don't know that the timing is really right – when we've been knocked down (economically) and are trying to get back up."

But Menéndez said the whole point is to prevent a repeat of the economic and health disaster.

"I know how hard times are financially, but we are in this mess (nationwide) because we didn't have a better response," he said. "What would we all be willing to pitch in if the next time a horrible pandemic was about to kick off, that we could shorten the time frame that we all have to go through this" by a substantial amount?

New imaging equipment aids TTUHSC's cancer research

by: Jason Britsch

Posted: Jan 19, 2021 / 04:16 PM CST / Updated: Jan 19, 2021 / 09:19 PM CST

AMARILLO, Texas (KAMR/KCIT) — The Texas Tech University Health Sciences Center in Amarillo is now one of just two facilities in the country in possession of revolutionary imaging equipment.

“This is a dream come true,” said Dr. Ulrich Bickel, TTUHSC Jerry H. Hodge School of Pharmacy Associate Dean of Sciences.

Dr. Bickel is referring to the new state-of-the-art imaging equipment.

The microscope system, which allows optical imaging of living cells, is just the first of three instruments that will help Texas Tech in its cancer research.

“Our colleagues here at the school of pharmacy are primarily interested in developing new drugs. This helps us watch these drugs into cells and the effects on cells that they have in cell culture. At this basic stage, this is a huge advance to be able to follow this into more detail,” said Dr. Bickel.

This was all made possible thanks to a \$2.8 million grant from the Cancer Prevention and Research Institute of Texas.

Dr. Bickel explains how closely they can now examine living cells.

“That little object that you can see through the microscope compared to a human hair is like if you take a human hair and compare it to a cable that’s like 10 inches in diameter,” said Dr. Bickel

Dr. Bickel said having the unique distinction of being just one of two facilities in the country with this equipment, will inspire collaboration with other institutes and in the process, medical breakthroughs.

“This is the only instrument that’s currently available in a wide region here. So we also hope that this will stimulate a lot of collaborations here in the future that we could have visitors once the COVID situation is over. We can connect to colleagues from other universities and other academic institutions. This is really something special,” said Dr. Bickel.

Dr. Bickel said the other two instruments will be installed and put to use in the coming months.

<https://www.myhighplains.com/news/local-news/new-imaging-equipment-aids-ttuhscs-cancer-research/>



FRESH FUNDS

Houston biotech startup raises millions to battle pediatric cancer



John Egan Jan 21, 2021, 10:48 am



Allterum Therapeutics Inc., a portfolio company of Fannin Innovation Studio, is using the funds to prepare for clinical trials. *Photo via Getty Images*

Alterum Therapeutics Inc. has built a healthy launchpad for clinical trials of an immunotherapy being developed to fight a rare form of pediatric cancer.

The Houston startup recently **collected \$1.8 million in seed funding** through an investor group associated with Houston-based Fannin Innovation Studio, which focuses on commercializing biotech and medtech discoveries. Allterum has also brought aboard pediatric oncologist Dr. Philip Breitfeld as its

chief medical officer. And the startup, a Fannin spinout, has received a **\$2.9 million grant** from the Cancer Prevention Research Institute of Texas.

The funding and Breitfeld's expertise will help Allterum prepare for clinical trials of 4A10, a monoclonal antibody therapy for treatment of cancers that "express" the interleukin-7 receptor (IL7R) gene. These cancers include pediatric acute lymphoblastic leukemia (ALL) and some solid-tumor diseases. The U.S. Food and Drug Administration (FDA) has **granted** "orphan drug" and "rare pediatric disease" designations to Allterum's monoclonal antibody therapy.

If the phrase "monoclonal antibody therapy" sounds familiar, that's because the FDA has **authorized emergency use of this therapy** for treatment of COVID-19. In early January, the National Institute of Allergy and Infectious Diseases **announced** the start of a large-scale clinical trial to evaluate monoclonal antibody therapy for treatment of mild and moderate cases of COVID-19.

Fannin Innovation Studio holds exclusive licensing for Allterum's antibody therapy, developed at the National Cancer Institute. Aside from the cancer institute, Allterum's partners in advancing this technology include the Therapeutic Alliance for Children's Leukemia, Baylor College of Medicine, Texas Children's Hospital, Children's Oncology Group, and Leukemia & Lymphoma Society.

Although many pediatric patients with ALL respond well to standard chemotherapy, some patients continue to grapple with the disease. In particular, patients whose T-cell ALL has returned don't have effective standard therapies available to them. Similarly, patients with one type of B-cell ALL may not benefit from current therapies. Allterum's

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antibody therapy is designed to effectively treat those patients.

Later this year, Allterum plans to seek FDA approval to proceed with concurrent first- and second-phase clinical trials for its immunotherapy, says Dr. Atul Varadhachary, managing partner of Fannin Innovation Studio, and president and CEO of Allterum. The cash Allterum has on hand now will go toward pretrial work. That will include the manufacturing of the antibody therapy by Japan's Fujifilm Diosynth Biotechnologies, which operates a facility in College Station.



"The process of making a monoclonal antibody ready to give to patients is actually quite expensive," says Varadhachary, adding that Allterum will need to raise more money to carry out the clinical trials.

The global market for monoclonal antibody therapies is projected to exceed \$350 billion by 2027, [Fortune Business Insight](#) says. The continued growth of these products "is expected to be a major driver of overall biopharmaceutical product sales," according to a [review](#) published last year in the *Journal of Biomedical Science*.

One benefit of these antibody therapies, delivered through IV-delivered infusions, is that they tend to

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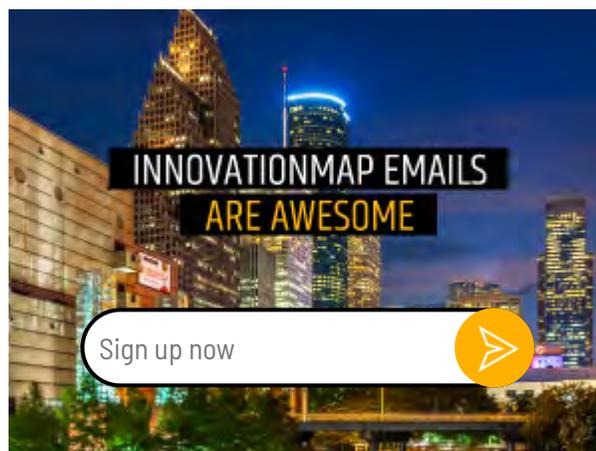
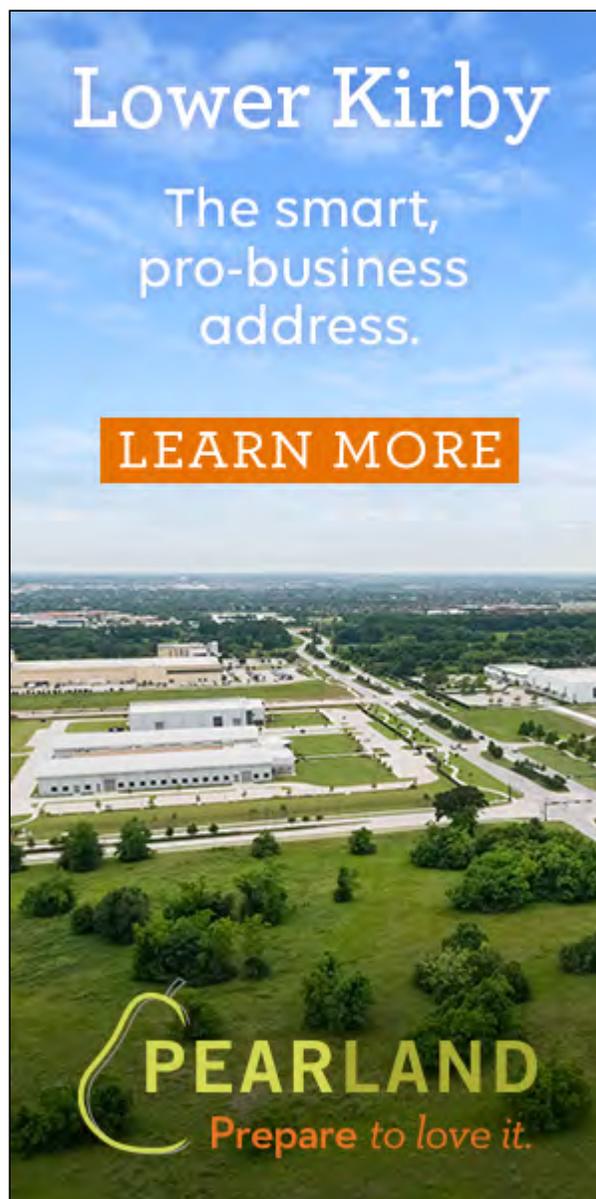
cause fewer side effects than chemotherapy drugs, the [American Cancer Society](#) says.

"Monoclonal antibodies are laboratory-produced molecules engineered to serve as substitute antibodies that can restore, enhance or mimic the immune system's attack on cancer cells. They are designed to bind to antigens that are generally more numerous on the surface of cancer cells than healthy cells," the [Mayo Clinic](#) says.

Varadhachary says that unlike chemotherapy, monoclonal antibody therapy takes aim at specific targets. Therefore, monoclonal antibody therapy typically doesn't broadly harm healthy cells the way chemotherapy does.

Allterum's clinical trials initially will involve children with ALL, he says, but eventually will pivot to children and adults with other kinds of cancer. Varadhachary believes the initial trials may be the first cancer therapy trials to ever start with children.

"Our collaborators are excited about that because, more often than not, the cancer drugs for children are ones that were first developed for adults and then you extend them to children," he says. "We're quite pleased to be able to do something that's going to be important to children."



OPINION *This piece expresses the views of its author(s), separate from those of this publication.*

Our view: State must be better prepared for next pandemic

AGN Media Editorial Board

Published 5:41 a.m. CT Jan. 24, 2021

The coronavirus pandemic has done more than ravage a state economy that continues to make a wobbly recovery. It also exposed weaknesses in preparation, response and, in some instances, communication throughout the state.

Virus cases continue to surge throughout the country, and a number of Texas communities have been hotspots with staggering stress on health care resources and a devastating loss of life. Just more than 34,000 Texans have died because of the virus as of late last week. Even with vaccines being distributed, the battle continues against COVID-19.

As a result, Texas would be well-served to be proactive in planning now for the next pandemic.

Toward that end, Sen. Jose Menendez, D-San Antonio, has proposed developing a state agency that would be funded with up to \$3 billion in taxpayer-backed bonds over 10 years. It would provide grants for research into emerging diseases and development of vaccines and other treatments for them, according to our story last week.

Although the nation has not faced a public health crisis of this magnitude in just more than a century, public health experts are convinced the country will likely face threats similar to the coronavirus in the years ahead. According to the World Health Organization, "COVID-19 will not be the world's last health emergency," making it important that what is described by WHO as the "panic-then-forget" cycle be broken. Past crises typically show that once an outbreak is controlled, the world turns to other important matters, undercutting preparedness measures.

"Over the years, we have had many reports, reviews and recommendations all saying the same thing: The world is not prepared for a pandemic. COVID-19 has laid bare the truth. When the time came, the world was still not ready," WHO Director-General Dr. Tedros Adhanom Ghebreyesus said during a virtual event last October. "This will not be the last pandemic, nor the last global health emergency."

13-21

In Texas, the new agency would be shaped along the lines of the Cancer Prevention and Research Institute of Texas, also known as CPRIT. Texas voters approved CPRIT in 2007, issuing \$3 billion in bonds of up to \$300 million per year to fund grants, according to our story. The agency's cancer-fighting efforts were renewed last year when an additional \$3 billion was authorized.

“Texas likes to pride itself in being forward-thinking and being a leader, so let's be a leader in response to any global pandemic or virus,” Menendez said in our story. “If we could have short-circuited this pandemic, how many lives would we have saved and how many fewer Texans would have died.”

Prior to the start of this year's session, Menendez filed Senate Bill 264, which would create an agency to be called the Texas Research Consortium to Cure Infectious Diseases. Issuing bonds to underwrite the agency's grants would require voter approval, as our story pointed out.

While Gov. Greg Abbott has not commented publicly on the proposal, the state needs to seriously look at preparedness measures that would head off a similar threat in the future. Investing now could result in significant savings later. Lawmakers understand this. Two years ago, in the first session following the devastation of Hurricane Harvey, legislators filed numerous bills aimed at recovery and preparedness.

The damage from COVID-19 has been much more widespread and continues to linger 10 months after the first cases appeared in Texas. The economic recovery is to a large extent at the mercy of the virus, and few expect a full recovery until the virus is under control. The state continues to ramp up vaccine distribution, but it's safe to say Texas is still months away, and possibly farther, from being on the other side of this crisis.

In the meantime, the state must apply what it has learned from the disruption of virtually every corner of life in Texas. That means moving forward and being better prepared, even in this budget cycle in which money is tight and priorities are numerous.

These threats from microscopic enemies, though, are not going away for a variety of reasons, and facing that proactively starts with state leaders. “Infectious disease threats are increasing – it's not an ‘if’ but a ‘when’ situation in terms of the emergence of another new deadly virus,” Larry Schlesinger, president of the nonprofit Texas Biomedical Research Institute, said in our story.

We understand the cost for this agency is a difficult ask in this budget cycle, but the idea is sound and worth exploring, especially if it leads to a path where Texas is truly ready the next time a pandemic erupts.



FUNDING NEWS

MEDICAL COUNTERMEASURES

DoD Awards Funding to Pulmotect to Study Repurposed PUL-042 Against COVID-19

by **Global Biodefense Staff** January 27, 2021, 9:53 am



Credit: Shutterstock

The Department of Defense (DOD) awarded a \$6 million agreement to Pulmotect, Inc., a clinical-stage biotechnology company, to execute two [ongoing Phase II trials](#) addressing COVID-19.

PUL-042, a synergistic combination of two toll-like receptor agonists, activates the lungs' surface immune system. As microbes, including viruses, land on the epithelial cells of the lung lining, they are destroyed on-contact by antimicrobial [13-23](#)

peptides and reactive oxygen species (ROS), including superoxides, that are released by epithelial cells. PUL042 has demonstrated protection against a broad range of respiratory pathogens in preclinical models, including the coronaviruses that cause MERS and SARS.

“We are delighted to receive funding from the Department of Defense to complete these clinical trials, both of which are enrolling participants at clinical sites in the U.S.,” said Dr. Colin Broom, CEO of Pulmotect. “We appreciate the support to evaluate PUL-042, which not only has the potential to be effective against SARS-CoV-2 but also also has potential for use against other pathogens that infect the respiratory tract.”

If the clinical trials generate positive data, Pulmotect will submit an emergency use authorization (EUA) to the U.S. Food and Drug Administration (FDA) for PUL-042 as a COVID-19 therapeutic in 2021.

The first study will test the prophylactic capabilities of PUL-042 by evaluating the efficacy and safety of the drug in reducing the infection rate of SARS-CoV-2 and its progression to COVID-19. The second is a therapeutic study testing the effectiveness of PUL-042 to reduce the severity of the disease in those with early and/or mild COVID-19 infection.

The agreement was executed by the DOD’s [Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense’s \(JPEO-CBRND\)](#) Joint Project Manager for Chemical, Biological, Radiological and Nuclear Medical (JPM CBRN Medical) through the Medical CBRN Defense Consortium, in collaboration with U.S. Army Contracting Command-New Jersey (W15QKN-16-9-1002, Project #MCDC 2006-002).

“The repurposing of this agent advances the fight against COVID-19, with the potential to protect our service members during this unprecedented pandemic,” said Col. Ryan Eckmeier, the Joint Project Manager for CBRN Medical.

“Facilitating our government and industry partners to help find a way to tackle this threat is a necessary action to reduce the spread of this disease.”

13-24

Pulmotect is developing PUL-042, a clinical stage, first-in-class, inhaled, immunomodulatory agent. A synergistic agonist that amplifies the innate immune defenses of the lung epithelial mucosa to provide broad-spectrum, pathogen-agnostic protection against respiratory infections. Invented at UT MD Anderson Cancer Center/Texas A&M University, PUL-042 has patents issued in 10 countries, both as a stand-alone composition of matter product and in combination with antivirals. PUL-042 R&D has been supported by the National Institutes of Health (NIAID, NIGMS), the Cancer Prevention and Research Institute of Texas (CPRIT), and other funding agencies.

#CLINICAL TRIALS #COVID COUNTERMEASURES #COVID-19 #EDITOR PICK #JPEO-CBRND #SARS-COV-2



MEDICAL COUNTERMEASURES | RESEARCH

SARS-CoV-2 Stem-Loop II Motif: Potential Target for Anti-viral Drugs

by **Global Biodefense Staff** January 26, 2021, 6:05 pm



CANCER INNOVATION

TMC cancer therapeutic accelerator names inaugural cohort

Laura Furr Mericas Feb 5, 2021, 11:24 am



The Texas Medical Center's Innovation Institute named 15 Texas companies to its new cancer-focused accelerator program. *Photo courtesy of TMCx*

The Texas Medical Center named 15 groundbreaking researchers and companies to its inaugural class of the Accelerator for Cancer Therapeutics on Thursday. All hail from the Lone Star State.

The ACT program is the only accelerator focused on cancer treatment at the earliest stages of commercialization, thanks to a \$5 million grant from the Cancer Prevention and Research Institute of Texas awarded to the TMC in the fall of 2019.

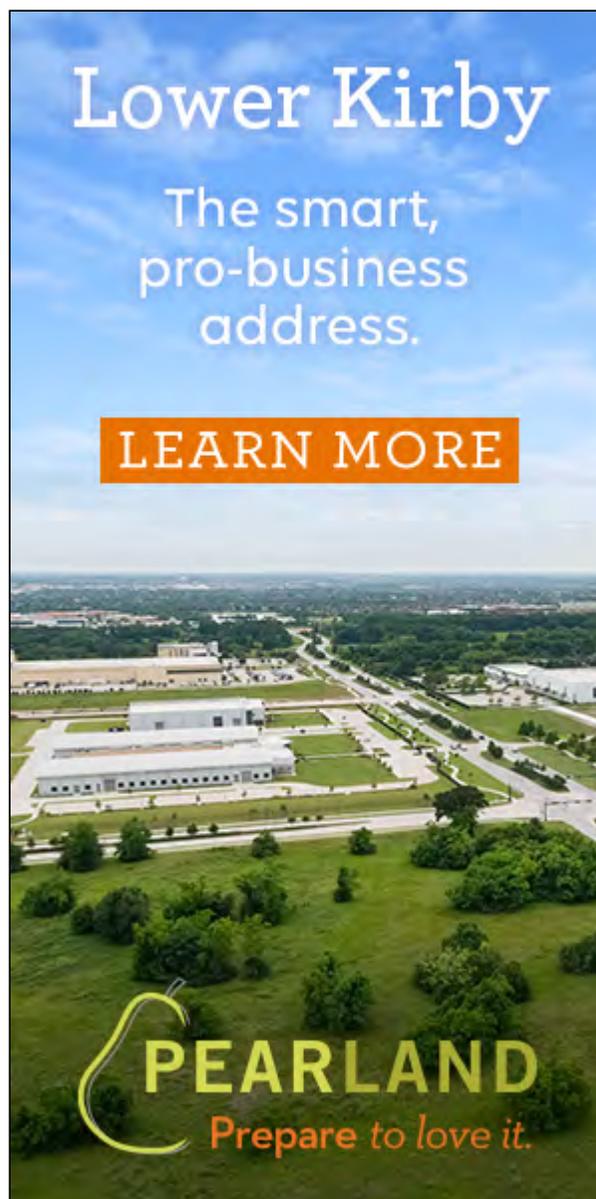
The nine-month program kicked-off at the end of January and will be run by TMC Innovation, according to a release from the TMC. It aims to provide the class with resources to help their oncology biotech projects reach new milestones, including even commercialization.

The inaugural cohort is made up of companies and researchers exploring immunotherapy, cell therapy, targeted therapy, cancer pain, and drug platforms. The group is split about evenly between companies and academic researchers. The group of Texans includes:

- Raptamer Discovery Group
- IDA Therapeutics
- Elbrus Therapeutics
- Parthenon Therapeutics
- Lokesh Battula
- Aumeta
- Autoimmunity Biologic Solutions
- Max Mamonkin
- Qing Yi
- Astero Alta
- TEZCAT Laboratories
- Anil Sood
- Coactigon
- Xiadong Cheng
- IonTx

At the end of the nine months, the class will present an integrated strategic plan and at least one grant submission. They will also have the opportunity to pitch investors and corporations.

The class will also gain support in grant writing, chemistry, and funding opportunities, as well as mentorship.



TRENDING NEWS

presented by **HR&P**

"As the past year has shown, the pace of scientific discovery can be blistering," says Tom Luby, director of TMC Innovation. "At the same time, successfully translating research into effective therapies available to patients requires a mix of business, technical and regulatory skills that may not typically be available to researchers.

"By linking the participants with mentors who can both advance their scientific work and support the technical needs, we expect this first class of ACT participants will make a meaningful difference for cancer patients in Texas and beyond."

TMCx, which is also run by TMC Innovation, recently **announced seven health tech companies that were selected to its 2021 class** of its health tech accelerator.

Broader in scope than the ACT accelerator, the TMCx startups focus on an array of subject matters from heart health to artificial intelligence to extremity rehabilitation.

ONLINE ONLY

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GOING PUBLIC

Tilman Fertitta takes much of his empire public in massive \$6.6 billion merger

GETTING AHEAD

Houston biotech startup announces merger and \$10M series A

BUILDING HOUSTON**WHAT'S IN STORE**

Look ahead to 2021's tech trends with Deloitte's experts